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IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

C.R. BARD, INC.,

Petitioner,

—v.—

M3 SYSTEMS, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a patentee's modification of its patented product within the scope of the patent which renders a competitor's technically related product incompatible with the patented modified product can constitute a violation of the antitrust laws?

2. Whether a split decision by the United States Court of Appeals for the Federal Circuit, finding a patent invalid under 35 U.S.C. § 102(b) because of an on-sale bar based upon a "totality of the circumstances" analysis, should be vacated and remanded for further consideration in light of the new on-sale criteria set forth in the Court's decision in *Pfaff v. Wells Elecs., Inc.*, ____ U.S. ____, 119 S. Ct. 304 (1998)?

PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this petition for writ of *certiorari*.

Petitioner is C.R. Bard, Inc. ("Bard"). Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company or subsidiaries.

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IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

C.R. BARD, INC., *Petitioner,*

v.

M3 SYSTEMS, INC., *Respondent.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

C.R. Bard, Inc. respectfully petitions for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals is reported at 157 F.3d 1340 (Fed. Cir. 1998), and is reproduced beginning at Appendix page 1a. The order of the court of appeals denying Bard's petition for rehearing and declining Bard's suggestion for rehearing *in banc* is not reported, and is reproduced beginning at Appendix page 90a. A separate opinion concurring in the order of the court of appeals denying the petition for rehearing and declining the suggestion for rehearing *in banc* is not reported, and is reproduced at Appendix page 92a. The judgment of the court of appeals is not reported, and is reproduced beginning at Appendix page 95a. The judgment of the district court is not reported, and is reproduced at Appendix page 97a.

JURISDICTION

The opinion of the United States Court of Appeals for the Federal Circuit issued on September 30, 1998. This Court's decision in *Pfaff v. Wells Elecs, Inc.*, ___ U. S. ___, 119 S. Ct. 304 (1998) issued on November 10, 1998. An order denying Bard's petition for rehearing and declining a suggestion for rehearing *in banc* was entered on December 7, 1998. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The statutory provisions involved in this Petition are 15 U.S.C. §§ 2 and 15(a), 35 U.S.C. § 102(b) and 28 U.S.C. § 2106.

15 U.S.C. § 2 provides in pertinent part:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 15(a) provides in pertinent part:

> Except as provided in subsection (b) of this section, any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee . . . .

35 U.S.C. § 102 provides in pertinent part:

> A person shall be entitled to a patent unless -
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or . . . .

28 U.S.C. § 2106 provides in pertinent part:

> The Supreme Court or any other court of appellate jurisdiction may affirm, modify, vacate, set aside or reverse any judgment, decree, or order of a court lawfully brought before it for review, and may remand the cause and direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had as many be just under the circumstances.

STATEMENT OF CASE

This Petition raises a fundamental question regarding the scope of United States antitrust and patent laws which will profoundly impact technological innovation and shape what constitutes lawful competition: whether a patentee's modification of its patented product within the scope of the patent which renders a competitor's technically related product incompatible with the patented modified product can be a violation of the antitrust laws?

The Petition also raises the question of whether, in view of this Court's holding in *Pfaff v. Wells Elecs., Inc.*, ___ U.S. ___, 119 S. Ct. 304 (1998), the split decision by the United States Court of Appeals for the Federal Circuit finding a patent invalid under 35 U.S.C. § 102(b) because of an on-sale bar based upon an analysis of the "totality of the circumstances" should be vacated and remanded for further consideration in light of the Court's new *Pfaff* on-sale test. Even though *Pfaff*, decided on November 10, 1998, criticized and ultimately rejected the "totality of the circumstances" on-sale analysis as unnecessarily vague, the Federal Circuit, on December 7, 1998, refused to reconsider its on-sale decision under the new *Pfaff* on-sale criteria. The Federal Circuit considered two alleged on-sale events in its decision. The first event was upheld as an on-sale bar by one member of the panel who did not comment on the second event. The second event was upheld as an on-sale bar by a second member of the panel who did not comment on the first event. The third member of the Federal Circuit panel found neither event constituted an invalidating on-sale bar.

A. The Patented Products

Bard's United States Patent No. RE 34,056 ("the '056 patent") is entitled "Tissue Sampling Device" and is directed to devices and needles for taking tissue samples from a patient for biopsy purposes. 2a. Radiplast was Bard's predecessor in interest with respect to the '056 patent. 2a, 6a.

In November 1984, while Radiplast and Hart Enterprises, a machine shop, were corresponding concerning the design and development of a new biopsy device and needles, Radiplast responded to an inquiry from a physician in the United States who had observed a demonstration and brochure describing an earlier, unpatented biopsy device. 29a. Radiplast sent the physician a brochure and informed the physician that it hoped that a new biopsy device and new needles would be available sometime in 1985. 29a, 70a-71a. Radiplast also quoted a price to the physician. 29a. No further correspondence took place between the physician and Radiplast. 29a.

At the time of the response, the new device and new needles, which became the subject of the '056 patent, were still in an "early development stage." 30a. No work had been done on the new biopsy device, and the invention was not close to completion. 23a, 30a. No drawings had been prepared describing the new biopsy device, and no prototype of either the new device or needles had been constructed. There were only preliminary drawings of the needle "concept" which were later changed. 27a, 72a-73a. The physician who made the inquiry was unaware of the differences between the earlier, unpatented device he observed and the new device and needles under development. 29a.

During the course of the patent infringement litigation in which it was alleged, *inter alia*, that M3 Systems, Inc. ("M3") infringed the '056 patent, Bard modified its new patented biopsy device so that it could not fire M3's accused infringing biopsy needles. The modified device, however, was still within the scope of the '056 patent. 58a-59a, 92a. M3 responded by developing an adapter that allowed its needles to be used in Bard's patented modified device. 58a.

B. The District Court Litigation

Bard sued M3 for patent infringement asserting that M3's biopsy device and biopsy needles infringed the '056 patent and a second U.S. Patent No. 4,944,308 ("the '308 patent"), not in issue here. 2a. M3 asserted that Bard's patents were invalid for a number reasons, and not infringed. 2a. M3 also asserted that Bard committed fraud on the U.S. Patent and Trademark Office ("PTO") in procuring the asserted patents, committed patent misuse and violated the antitrust laws. 2a.

The jury rendered special verdicts in M3's favor on every issue. Specifically, the jury rendered special verdicts finding the '056 patent invalid and not infringed on the following grounds: anticipation (35 U.S.C. § 102(e)); obviousness (35 U.S.C. § 103); violation of the on-sale bar provision (35 U.S.C. § 102(b)); incorrect naming of inventors; and non-compliance with the reissue requirements (35 U.S.C. § 251). 2a-3a. The jury also rendered verdicts finding the '308 patent invalid and not infringed on the following grounds: anticipation (35 U.S.C. § 102(b)); obviousness (35 U.S.C. § 103); and insufficient written description (35 U.S.C. § 112, ¶6). 3a. The jury further found that Bard committed fraud in obtaining the '056 and '308 patents, misused the patents and committed three separate antitrust violations: (1) attempting to enforce fraudulently

obtained patents ("Walker Process claim"); (2) commencing an infringement action knowing that the asserted patents were invalid, unenforceable and not infringed ("sham litigation claim"); and (3) modifying its biopsy devices within the scope of the '056 patent so that M3's replacement needles were incompatible with Bard's patented modified biopsy device unless an adapter was used ("attempt to monopolize claim"). 3a. The jury awarded $1.5 million in antitrust damages which was trebled by the trial court. 3a.

C. Post-Verdict Decision Of Trial Court

Bard filed post-trial motions seeking judgments as a matter of law on all validity, infringement, enforceability and antitrust issues. The trial court denied these motions without opinion. 3a.

D. Federal Circuit Opinion

On appeal, a panel of the United States Court of Appeals for the Federal Circuit unanimously reversed the jury verdicts that the '056 patent was invalid on the following grounds: anticipation (35 U.S.C. § 102(e)); obviousness (35 U.S.C. § 103); incorrect naming of inventors; and non-compliance with the reissue requirements (35 U.S.C. § 251). 13a, 16a, 19a, 22a. The jury verdict of noninfringement of the '056 was vacated. 31a. With respect to the '308 patent, the Federal Circuit unanimously reversed the jury verdicts of anticipation (35 U.S.C. § 102(b)); obviousness (35 U.S.C. § 103) and insufficient written description (35 U.S.C. § 112, ¶ 6). 36a, 37a, 39a. The Federal Circuit also unanimously reversed the jury verdicts of fraud on the PTO and patent misuse, as well as the verdicts relating to M3's Walker Process and sham litigation antitrust claims. 51a, 53a-54a, 55a-56a.

In a split two-to-one decision, the majority upheld the jury verdict that Bard violated the antitrust laws by modifying its new biopsy device so that it could not accept M3's replacement biopsy needles even though the modified device was still covered by the '056 patent, and M3's needles were accused of infringing that patent.[1] 86a-88a. Judge Bryson's majority opinion ignored the limited period of exclusivity guaranteed a patentee, and held that Bard engaged in "predatory" conduct because M3's replacement needles were incompatible with the patented modified device unless used with an adapter:

> Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of "copycat" needles. 88a.

In contrast, Judge Newman in her dissenting opinion (56a-62a) observed that Bard had "no duty to facilitate M3's competition by refraining from changing its products." 57a. The dissent acknowledged that both Bard's modified device and new needles were covered by the '056 patent, and forcefully emphasized the rights guaranteed Bard as a patentee:

> Both the needle assembly alone and the integrated biopsy gun/needle device were patented. They were subject to Bard's patent-based rights to exclude others from making, using, or selling them. It was not Bard's changes to its biopsy gun or needles that affected M3's sale of replacement needles; it was

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[1] Because the Federal Circuit unanimously reversed two of the three antitrust verdicts, the antitrust damages award was vacated and remanded for reallocation. 3a, 89a.

> the patents on these products. To hold that Bard could violate the Sherman Act by changing these products, if M3's business was adversely affected, is a novel and pernicious theory of antitrust law that is contrary to the principles of competition, and fraught with litigation-generating mischief. 59a.

The dissent emphasized that the majority had "created a new, vague and unworkable" cause of action (59a):

> It is without precedent to find antitrust liability premised on a theory that development of new products is illegally anticompetitive when the new product requires competing suppliers to adjust their product accordingly. 62a.

In a concurring opinion to the Federal Circuit's order denying Bard's petition for rehearing and suggestion for rehearing *en banc*, Federal Circuit Judges Gajarsa and Clevenger suggested that the only argument raised on appeal by Bard relating to the antitrust cause of action was the sufficiency of evidence.[2] 93a. The concurrence, however, acknowledged that "floodgates with respect to a new antitrust cause of action" could be opened if the majority's opinion was not narrowly construed. 93a.

In a second split decision, two separate opinions based upon different events and different legal theories, upheld the jury verdict that the '056 patent was invalid under the on-sale provision of 35 U.S.C. § 102(b). Chief Judge Mayer rendered an opinion holding that Radiplast's response to the physician's inquiry regarding the earlier, unpatented biopsy device amounted to an invalidating on-sale bar. 68a-

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[2] However, no amount of evidence can be sufficient to support an antitrust theory that is erroneous as a matter of law.

78a. Chief Judge Mayer's opinion, however, was silent concerning a second later alleged on-sale event involving Radiplast's transfer of 250 needles for use in clinical testing. The opinion by Judge Bryson took "a somewhat different analytical path" (79a) and found that the transfer of 250 needles for clinical testing constituted an on-sale bar, but did not address whether Radiplast's letter to the physician was also an invalidating on-sale bar. 79a-85a. Thus, neither Radiplast's response nor Radiplast's transfer of needles for clinical testing was found by both opinions to constitute an on-sale bar pursuant to 35 U.S.C. §102(b). The dissenting opinion by Judge Newman (22a-31a) found no substantial evidence that either event was an on-sale bar under 35 U.S.C. § 102(b), and maintained that both verdicts of invalidity based upon Section 102(b) were "incorrect." 31a.

Chief Judge Mayer's opinion finding Radiplast's response to the physician's inquiry amounted to an on-sale bar was expressly premised upon an analysis of the "totality of the circumstances": "the ultimate determination of whether an on sale bar exists rests on the totality of the circumstances" (69a), and "the totality of circumstances supports the ultimate legal conclusion." 70a. The dissent, however, maintained that Radiplast's response was not an on-sale bar because the new biopsy device and needles were still in an "early development stage" and if an order was placed in November 1994, the order "could not have been filled at that time." 29a-30a.

Judge Bryson's opinion held that Radiplast's transfer of 250 needles for clinical testing "constituted a sale" which did not fall "within the experimental purpose exception," and suggested that the "primary purpose" for Radiplast's transfer was "to market the patented invention," not to conduct tests to determine whether the invention "would work for its intended purpose." 83a. Judge Bryson, in reaching his

conclusion, implicitly applied the "totality of the circumstances" test and considered "various factors" surrounding the transfer made in preparation for the required clinical testing including, *inter alia*, that Radiplast paid for the needles involved in the tests, that Radiplast provided a bulk quote for needles, that the clinical testing was conducted by Radiplast, that Radiplast was not aware of the identity of the patients, and that there was no evidence of any secrecy agreements with the hospitals where the clinical tests were conducted. 82a-83a.

The dissent observed that the clinical tests were conducted after the critical date, all unused needles were destroyed at the test's conclusion, a collaborative relationship existed between Pharmaseal, the company which conducted the tests, and Radiplast, and the transfer "produced no profit for Radiplast." 25a-26a. The dissent also opined that "cost defrayal arrangements between collaborators are not deemed to be invalidating sales." 26a. In concluding that the transfer of needles for clinical testing was not an on-sale bar, the dissent stressed that:

> the sole purpose of this transaction was to make the devices available to the four selected hospitals for a limited test period. Radiplast's arrangement with Pharmaseal for payment or defrayal of the cost of providing the devices was not a sale or offer of sale as contemplated by section 102(b). 26a.

The dissent also acknowledged the uncertainty resulting from a "totality of the circumstances" analysis as evidenced by the panel's three disparate legal conclusions on the on-sale issue:

> The three different views in the three opinions of this panel on the on-sale issue point up the need for

> a more certain law than today exists. Inventors and those who commercialize inventions should reasonably know when the on-sale bar starts to accrue, instead of awaiting litigation-borne *post hoc* judicial evaluations of the totality of circumstances, varying with the nature of the invention, the nature of the customer contact, and the judicial weight given to conflicting policy interests. 31a n.5.

Although the Federal Circuit had the benefit of this Court's decision in *Pfaff* when it considered Bard's petition for rehearing and suggestion for rehearing *in banc*, it refused to reconsider the on-sale issue in light of the new, more definite on-sale criteria enunciated in *Pfaff*.

REASONS FOR GRANTING THE WRIT

This Court should grant certiorari to decide (1) whether a patentee's modification of its patented product within the scope of the patent which renders a competitor's technically related product incompatible with the patented modified product can be a violation of the antitrust laws? and (2) whether a split decision of the United States Court of Appeals for the Federal Circuit, finding a patent invalid under 35 U.S.C. § 102(b) as a result of an on-sale bar based upon an analysis of the "totality of the circumstances," should be vacated and remanded for further consideration in light of *Pfaff's* more definite on-sale criteria?

The decision formulated by the majority regarding the incompatibility of M3's replacement needles with Bard's patented device finds no support in law or fact, and if permitted to stand will significantly expand the reach of the antitrust laws far beyond the precedent of this Court and will dramatically curtail the constitutionally based protection afforded a patentee. The decision will stifle the

emergence of new technology, transform ordinary product development and technological innovation into potential antitrust violations necessitating judicial involvement in research and development decisions and flood the courts with antitrust litigation on behalf of competitors with inferior products or no patent protection in the hope of obtaining treble damages based upon the Federal Circuit's new theory of antitrust liability.

Additionally, the Federal Circuit's split decision upholding the verdict of an on-sale bar, premised upon an analysis of the "totality of the circumstances" cannot stand in view of this Court's decision in *Pfaff*.

I. The Federal Circuit Has Created A New Antitrust Cause Of Action Which Severely Narrows The Scope Of Protection Afforded By The Patent Laws

Relying upon a single decision,[3] the Federal Circuit's majority opinion has recast the scope of the antitrust laws[4] to

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[3] The majority's reliance upon *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965 (N.D. Cal. 1979), *aff'd sub nom.* 698 F.2d 1377 (9th Cir. 1983) in support of its improper judicial legislation in the antitrust arena is misplaced. 87a. As the dissent correctly observed (60a), the court held that the changes in IBM's product which prevented use of the competitor's peripheral devices "were not unreasonably restrictive of competition," and did not violate the Sherman Act. 698 F.2d at 1382.

[4] Section 2 of the Sherman Act, 15 U.S.C. § 2, makes it an offense to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce . . . ." *See, e.g., Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 454 (1993). To support an attempted monopolization claim, it must be demonstrated that a party a) engaged in predatory or unlawful conduct, b) possessed a specific intent to monopolize and c) possessed a dangerous probability of achieving monopoly power. *Id.* at 456.

encompass a new antitrust cause of action which ultimately restricts the protection afforded a patentee. The decision will chill technological innovation by extending antitrust liability to inventors of new patented technology which is incompatible with a competitor's existing technology. In this case, M3 made an adapter at low cost which allowed its needles to be used in Bard's patented modified device, resulting in increased needle sales for M3. M3 also had the option of supplying a needle which was compatible with Bard's modified device, even without an adapter, by offering a copy of the Bard needle. M3's own antitrust expert admitted that, in the absence of Bard's patent, M3 "could effectively compete" against Bard. 56a-57a. *See, e.g., Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (antitrust laws are designed to protect competition, not competitors); *Spectrum Sports*, 506 U.S. at 458 (the Sherman Act is not designed "to protect business from the working of the market; it is to protect the public from the failure of the market"). Lost in the majority's analysis and resulting expansion of the scope of antitrust law is the countervailing statutory protection afforded a patentee to exclude competitors from making, using or selling its patented technology. 57a-58a, 62a. *See Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1218 (9th Cir. 1997) ("failure to give any weight to . . . intellectual property rights in the jury instructions constitutes an abuse of discretion"), *cert. denied*, 118 S. Ct. 1560 (1998).

The '056 patent covers the modified biopsy device, and the needles used with that device. 59a. That patent affords Bard the right to exclude M3 and other competitors from making, using or selling the products covered by the '056 patent, including the needles used in the modified biopsy device. *See, e.g., Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510, 513 (1917)

(patent restrains "others from manufacturing, using, or selling that which he has invented" and provides patentee "exclusive use of just what his inventive genius has discovered"). However in affirming the jury verdict, the majority penalized Bard simply because it sought to reap the benefits of its valuable patent rights. 2a (Bard's patented biopsy devices and needles "have achieved commercial success"). *See, e.g., United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966) (antitrust laws are designed to protect monopolies premised upon "growth or development as a consequence of a superior product, business acumen, or historic accident"). Any alleged competitive disadvantage to M3's replacement needles resulted from Bard's rights as a patentee, not any perceived "predatory" conduct on behalf of Bard. *See Spectrum Sports*, 506 U.S. at 457 ("proof of unfair or predatory conduct alone" is not sufficient to make out the offense of attempted monopolization); *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816 (1945) (the limited period of exclusivity afforded a patentee "is an exception to the general rule against monopolies").

By disregarding Bard's rights as a patentee, the majority has created a new antitrust cause of action premised upon the alleged technological incompatibility of competing products.[5] Such a new cause of action finds no support in law or fact. 62a. The introduction of new technology, even if incompatible with a competitor's existing technology, is alone neither predatory nor anticompetitive. *See Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 542

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[5] An unlawful tying arrangement exists when an unpatented product must be used or purchased in order to obtain a patented product, thereby suppressing competition in the market of the tied or unpatented product. *See generally Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488 (1940).*

(9th Cir. 1983) ("standing alone, such technological interrelationship among complementary products is [not] sufficient to establish" an unlawful tying arrangement), *cert. denied*, 465 U.S. 1038 (1984). The "creation of technological incompatibilities" fosters competition by forcing competitors to develop new and improved technology. *See, e.g., Foremost Pro Color*, 703 F.2d at 542. This is particularly true when the new product or technology is protected by a patent. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (patent laws balance "the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy"). As observed in *Foremost Pro Color*:

> a firm that pioneers new technology will often introduce the first of a new product type along with related, ancillary products that can only be utilized effectively with the newly developed technology. Until other, less technologically advanced competitors procure licenses or otherwise develop ancillary products that are compatible with the new product, the technological leader will be faced with no present competition in the newly developed product market. 703 F.2d at 542.

In the present case the modified biopsy device and new needles used with that device are covered by Bard's '056 patent providing a limited period to exclude competitors from making, using or selling the needles used with Bard's patented modified device. *See, e.g., United States v. General Electric Co.*, 272 U.S. 476, 485 (1926) ("under the patent law the patentee is given by statute a monopoly of making, using and selling the patented article"). Therefore, Bard should not be penalized because M3's replacement needles were

incompatible with the patented modified biopsy device. *See Hirsh v. Martindale-Hubbell, Inc*, 674 F.2d 1343, 1348 (9th Cir.) (antitrust laws are not "intended to strike at all practices tending to improve a firm's market position"), *cert. denied*, 459 U.S. 973 (1982). M3's perceived harm results from the protection afforded by the patent laws, not an antitrust violation by Bard. *See Brooke Group*, 509 U.S. at 225 ("[e]ven an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws").

In considering whether development of a new product or technology can be unlawfully predatory and anticompetitive, it has been observed that "no administrable rule could be fashioned that would not exact an unreasonably heavy toll in the creation of incentives to innovate." 3 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law*, § 705b, p.157 (rev. ed. 1996). Similarly, courts which have addressed the interaction between the patent laws and antitrust laws have opined that the development of new products should not run afoul of the antitrust laws. *See, e.g., Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 164 (1995) ("It is the province of patent law . . . to encourage invention by granting inventors a monopoly over new product designs . . . for a limited time . . . ."); *United States v. Microsoft Corp.*, 147 F.3d 935, 948 (D.C. Cir. 1998) (recognition of the "undesirability of having courts oversee product design" because "any dampening of technological innovation would be at cross-purposes with antitrust law"); *Foremost Pro Color*, 703 F.2d at 542 ("[t]he creation of technological incompatibilities, without more, does not foreclose competition"); *Transamerica Computer Co. v. International Business Machs., Corp.*, 698 F.2d 1377, 1382 (9th Cir.) (design changes "were not unreasonably restrictive of competition"), *cert. denied*, 464 U.S. 955 (1983); *See also Northeastern Tel. Co. v. American*

Tel. and Tel. Co., 651 F.2d 76, 93 (2d Cir. 1981) ("considerable caution" should be exercised in determining whether the introduction of new products violates the Sherman Act), *cert. denied*, 455 U.S. 943 (1982). Implicit in these decisions is the court's reluctance to be thrust into the decisions involving, and the ramifications of, technological innovation and product development. *See, e.g., Microsoft,*, 147 F.3d at 949 ("the court should [not] embark on product design assessment" because "the courts have recognized the limits of their institutional competence and have on that ground rejected theories of 'technological tying'"); *ILC Peripherals Leasing Corp. v. International Business Machs. Corp.*, 458 F. Supp. 423, 439 (N.D. Cal. 1978) (the court should not become "enmeshed 'in a technical inquiry into the justifiability of product innovations'" where there is a difference of opinion regarding the advantages of competing innovations), *aff'd sub nom.* 636 F.2d 1188 (9th Cir. 1980) (citation omitted).

Bard's '056 patent covers both the biopsy device and the needles to be used with it, providing Bard the right to exclude all competitors from making, using or selling needles for use with the patented biopsy device. Although the Federal Circuit's dissent acknowledged that "antitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation" (62a), the majority has created a new antitrust cause of action that expands the scope of impermissible conduct and strikes at the very heart of statutory grant provided by the patent laws which are designed to "promote the Progress of Science . . . ." *See* U.S. Const., art. I, § 8, cl. 8. The majority opinion broadly proclaims that the development and sale of a patented product can constitute an antitrust violation while totally ignoring the ramifications of its judicial fiat, and by completely disregarding the admonition of the Court in

Spectrum Sports "to avoid constructions of § 2 which might chill competition, rather than foster it." 506 U.S. at 458. Under the Federal Circuit's majority opinion, a portion of a patentee's statutory right will be judicially taken away if the patentee's new patented technology is incompatible with a competitor's existing technology. *See SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) ("[n]o court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent"), *cert. denied*, 455 U.S. 1016 (1982). The prospect of subjecting a patentee to treble damages simply because its new patented technology is incompatible with a competitors existing technology, will undermine a patentee's "incentive . . . to risk the often enormous costs in terms of time, research, and development," thereby casting a pall over innovation and the development of new products. *See Kewanee Oil Co. v Bicron Corp.*, 416 U.S. 470, 480 (1974).

The new antitrust theory of product incompatibility created by the Federal Circuit's majority decision violates both patent and antitrust policy and if not reversed will have a chilling effect on product development and stifle technological innovation.

II. The Federal Circuit's Split On-Sale Decision Based On A "Totality Of The Circumstances" Analysis Is Contrary To This Court's Precedent In *Pfaff* And Must Be Vacated And Remanded

The "totality of the circumstances" on-sale test was criticized by the Court in *Pfaff v. Wells Elecs, Inc.*, ___ U.S. ___, 119 S. Ct. 304 (1998) as "unnecessarily vague." *Id.* at 310 n.11. In its place this Court promulgated a more definite two prong test which, if satisfied prior to the critical date, results in an invalidating on-sale bar: 1) "the product must be subject to a commercial offer for sale" and 2) "the invention

must be ready for patenting." *Id.* at 311-12. The Court noted that the second prong of this test could be satisfied in at least two ways:

> by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. *Id.* at 312.

Federal Circuit Chief Judge Mayer's opinion finding Radiplast's response to the physician's inquiry to be an on-sale bar expressly relied upon the application of the "totality of the circumstances" test. 69a, 70a. Even though this Court criticized the "totality of the circumstances" test in *Pfaff* on November 10, 1998, the Federal Circuit on December 7, 1998 refused to reconsider the panel's on-sale decision in light of the new *Pfaff* criteria. When Radiplast's actions are analyzed under the new two prong *Pfaff* test, there is insufficient evidence to satisfy the requirements of either prong.

When Radiplast responded to the physician's inquiry regarding the earlier, unpatented biopsy device, the new biopsy device and needles were only a concept still in an "early development stage" and were not capable of being commercially exploited. 29a-30a. *See, e.g., RCA Corp. v. Data General Corp.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989) (there can be no offer if there is "only a mere concept of the invention"); *UMC Elecs. Co. v. United States*, 816 F.2d 647, 657 (Fed. Cir. 1987) (an inventor with "merely a conception" or who was working "towards development of that conception" does not have invention to offer for sale), *cert. denied*, 484 U.S. 1025 (1988). The inclusion of a proposed price for a product still under development which Radiplast

hoped to market in the future did not transform the response into a commercial offer for sale sufficient to invalidate the '056 patent. *See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1270 (Fed. Cir. 1991) (discussion of price and quantity "does not of itself place the subject matter 'on sale' in the sense of § 102(b)"). Radiplast's response failed to refer to any delivery terms, payment terms or warranty and simply represented a desire or intent to sell a new biopsy device in the future after the product had been developed and adequately tested. *See Intel Corp. v. U.S. Int'l. Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991) ("not a violation of the on-sale bar to make preparations for sale"). Radiplast's response regarding the earlier, unpatented biopsy device did not amount to a commercial offer to sell the new patented biopsy device and needles then under development and, therefore, fails to satisfy the first prong of the *Pfaff* test.

At best Radiplast's response amounted to an ambiguous offer which falls far short of the requisite definite "commercial offer for sale" required by *Pfaff*. 119 S. Ct. at 311; *See RCA*, 887 F.2d at 1062 ("definite offer to sell . . . essential" and excludes "merely indefinite or nebulous discussion about a possible sale"). The ambiguity of Radiplast's response is evidenced by the brochure accompanying the response. Even in his opinion, Federal Circuit Chief Judge Mayer stated that the brochure resulted in "ambiguity" because it could not be determined whether it described the earlier biopsy device or the new device under development. 72a. The indefinite nature of the response is further confirmed by the physician who testified he knew nothing about the differences between the earlier device and new biopsy device under development. 29a. *See King Instrument Co. v. Otari Corp.*, 767 F.2d 853, 860 (Fed. Cir. 1985) (when an executory sales contract is offered before the

critical date, the prospective "purchaser must know how the invention embodied in the offer will perform"), *cert. denied*, 475 U.S. 1016 (1986). Radiplast's ambiguous response to an inquiry regarding the earlier, unpatented device clearly does not approach a definite commercial offer to sell the new biopsy device and needles required by the *Pfaff* test.

There was also no evidence that the invention of the '056 patent was "ready for patenting" in November 1984. Although Radiplast was in the process of exchanging preliminary drawings of its needle "concepts" with a machine shop (73a), there was no evidence that these drawings, or any other description of the proposed needles at this time, were "sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff*, 119 S. Ct. at 312. The drawings and existing description of the proposed needles simply did not rise to the level of "detailed engineering drawings" that "fully disclosed the invention" required by *Pfaff*. 119 S. Ct. at 307, 312. There were no drawings or written descriptions whatsoever of the patented biopsy device with which the needles were to be used until at least March of 1985. Moreover, the new device and needles of the '056 patent had not yet been reduced to practice when Radiplast responded to the physician's inquiry. The needles were only in an "early development stage" and the preliminary drawings of the needles were later changed. 27a, 30a. No prototype needles had been made. *See, e.g., Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 383 (1928) ("A machine is reduced to practice when it is assembled, adjusted and used."). Even after the device and needles were constructed, they had to be subjected to clinical testing to ensure that the needles worked satisfactorily for their intended purpose. 26a. *See Newkirk v. Lulejian*, 825 F.2d 1581, 1583 (Fed. Cir. 1987) (reduction to practice requires "more than theoretical capability" and "requires showing that

the apparatus . . . actually existed and worked for its intended purpose"); *See also Ethicon, Inc. v. United States Surgical Corp.*, 762 F. Supp. 480, 506-07 (D. Conn. 1991) (invasive medical device inventions must be tested on humans to determine whether they work for its intended purpose), *aff'd*, 956 F.2d 1065 (Fed. Cir. 1992).

At the time of Radiplast's response to the physician, the invention of the '056 patent was not "ready for patenting." Therefore, under *Pfaff*, Radiplast's response was not an on-sale bar pursuant to 35 U.S.C. § 102(b). Since Federal Circuit Chief Judge Mayer's conclusion that Radiplast's response to the physician constituted an on-sale bar under the "totality of the circumstances" analysis was critical to the Federal Circuit's plurality decision upholding the jury verdict of invalidity under 35 U.S.C. § 102(b), the Federal Circuit's on-sale decision should be vacated and remanded for further consideration in light of *Pfaff*.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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February 26, 1999

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

96-1165

C.R. BARD, INC.,

Plaintiff-Appellant,

v.

M3 SYSTEMS, INC.,

Defendant-Appellee.

DECIDED: September 30, 1998

Before MAYER, Chief Judge,
NEWMAN and BRYSON, Circuit Judges.

Opinion for the court by Judge Newman except for Part I.E (on-sale issue) and Part VI.C (attempt to monopolize). Judge Bryson does not join Parts I.A-D of Judge Newman's opinion. The district court's judgment concerning the on-sale bar is affirmed in separate opinions by Chief Judge Mayer and Judge Bryson. The district court's judgment concerning the attempt to monopolize issue is affirmed-in-part by Judge Newman's opinion (Parts VI.A-B), which Chief Judge Mayer and Judge Bryson join, and reversed-in-part by Judge Bryson's opinion (Part II), which Chief Judge Mayer joins. Judge Newman dissents with respect to the on-sale bar and attempt to monopolize issues.

NEWMAN, Circuit Judge.

In suit are United States Patent No. 4,944,308 issued July 31, 1990 (the '308 patent) and United States Reissue Patent No. RE 34,056 issued September 8, 1992 (the '056 patent), both entitled "Tissue Sampling Device." These patents originated with the work of Dr. Per Gunner Lindgren, a physician in Sweden, and are now owned by appellant C.R. Bard, Inc.

The patented inventions are devices for taking samples of body tissue for biopsy purposes, wherein a biopsy needle firing device or "gun" mechanically injects a biopsy needle assembly into the core body tissue. These devices are described as improving the speed, accuracy, ease, and patient comfort of tissue sampling, compared with manually inserted biopsy needles. They are said to be particularly advantageous for sampling small or movable lesions and fibrous or firm tissues, because the rapidly and firmly fired needles can penetrate even fibrotic lesions before the lesions can slip aside. The patented guns and needles have achieved commercial success.

Bard sued M3 Systems in August 1993 in the United States District Court for the Northern district of Illinois,[1] asserting that M3's ProMag biopsy gun and ACN/SACN biopsy needle assemblies infringed the '308 and '056 patents, respectively. M3 raised the defenses that the patents are invalid on several grounds and are not infringed, and also charged Bard with fraud, antitrust law violation, and patent misuse. The jury rendered special verdicts in favor of M3 on every issue, finding the '056 patent invalid and not infringed on each of the grounds of anticipation, obviousness, violation of a section 102(b) bar,

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[1] C.R. Bard, Inc. v. M3 Sys., Inc., No. 93-CV-4788 (N.D. Ill. Oct. 2 & Dec. 20, 1995) (orders).

incorrect naming of inventors, and non-compliance with reissue requirements; and finding the '308 patent invalid and not infringed on grounds of anticipation, obviousness, and insufficient written description. The jury also found that Bard perpetrated fraud in the Patent and Trademark Office (PTO) in obtaining both patents, that Bard misused both patents, and that Bard violated antitrust law, awarding $1.5 million in antitrust damages, trebled by the district court.

The district court denied all post-trial motions. This appeal followed. This court affirms the judgment of invalidity of the '056 patent and vacates the judgment of noninfringement of the '056 patent. The judgment of invalidity of the '308 patent is reversed and the judgment of noninfringement is affirmed. The judgments of misuse and fraud are reversed. The judgment of antitrust violation on the ground of attempt to monopolize is affirmed, but the antitrust damages award is vacated, for redetermination upon remand.

THE PATENTED INVENTIONS

The First Generation Device - The PCT Patent Application

In 1981 Dr. Lindgren, working in Sweden with Jan Allard, an engineer, designed and constructed the first of several successively improved mechanical biopsy guns. This "first generation" gun was designed to fire a commercially available biopsy needle assembly made by the Baxter Travenol Company, having the brand name "Tru-Cut." The Tru-Cut is a double needle consisting of a hollow outer needle called the cannula and an inner needle called the stylet. The stylet is solid except for a recess near its point. In the manual procedure for which the Tru-Cut

was designed, the physician would first extend the stylet and insert the assembly into the body tissue, whereupon the tissue to be sampled would flow into the recess in the stylet: the physician would then push the cannula into the body tissue to surround the stylet and cut and trap the tissue sample in the recess.

This procedure required the physician to use both hands to manipulate the needles, while a second physician would hold and manipulate the ultrasound equipment that is usually required to view the interior of the body and direct insertion of the needles. Dr. Lindgren sought to mechanize this procedure in order to improve the speed and accuracy of insertion, to reduce human error, and to permit a physician to perform the biopsy without assistance by providing a sampling device that can be operated with one hand while the other hand holds the ultrasound apparatus.

The first generation gun is a box-like structure fitted with two spring-loaded drivers associated with slots that are configured to hold the cannula and stylet of the Tru-Cut needle assembly. To use this gun the physician must first "cock" each of the spring-loaded drivers. This cocking action, as it was often called at trial, is referred to as pretensioning or energizing in the patent documents. Cocking is performed by hand or with a specially designed tool described as a miniature crowbar. After the drivers are cocked, the stylet and cannula are placed in the appropriate slots and the gun housing is closed. The gun is then aimed at the target tissue and a trigger mechanism releases the stylet and cannula in rapid sequence. The needles are then manually retrieved.

Dr. Lindgren and Mr. Allard filed a patent application on the first generation gun under the Patent Cooperation Treaty (PCT). The invention was assigned to

Radiplast AB, a small Swedish company associated with Dr. Lindgren. The PCT application was filed on March 31, 1982 and was published on October 13, 1983. It is prior art to the United States patent in suit.

The Second Generation - The '056 Reissue Patent

Starting in 1984, Dr. Lindgren undertook to improve the gun so that it would not be necessary for the physician to cock the two drivers manually before installing the biopsy needles, a step described as awkward and inefficient. In 1985 Dr. Lindgren, working with Dan Åkerfeldt, an engineer, designed a mechanism whereby the drivers are cocked by external action after the needles are placed in the gun and the housing is closed. In this mechanism rods are attached to each of the spring-loaded drivers, extend out the back of the gun, and culminate in a ring or handle. By pulling the ring or handle the operator simultaneously cocks both drivers, moving the needles rearward. A trigger mechanism then fires the stylet and cannula, in rapid sequence, into the tissue to be sampled.

The Tru-Cut needles were not usable with the second generation gun, for their structure was such that they could not be moved rearward as well as propelled forward. New needles were designed with a modified hub and flange structure and a slit in the stylet flange to facilitate placement in the gun. Corresponding structural changes were made to the gun to accommodate the changes in the needles. Radiplast, as assignee, filed a patent application in Sweden on February 19, 1986. The United States application was filed on July 30, 1986, naming Dr. Lindgren as the inventor. Corresponding United States Patent No. 4,699,154 (the '154 patent) was issued on October 13, 1987, with claims to the combination of the

second generation gun and the new needle assembly. The '154 patent did not claim the needle assembly alone.

In 1989 Bard, having become Radiplast's distributor in 1987, acquired ownership of the Radiplast patents. Bard applied for reissue of the '154 patent in order to add claims to the needle assembly alone. This reissue patent issued on September 8, 1992, and is the '056 patent in suit. During the reissue proceeding Bard and Dr. Lindgren petitioned the PTO to correct the inventorship to include Dan Åkerfeldt. In addition, Bard described to the PTO various activities of Radiplast in the United States, as shall be discussed in connection with the on-sale issue.

The Third Generation Gun - The '308 Patent

Dan Åkerfeldt continued to work on improving these devices. He sought to make the gun easier to use, especially by inexperienced physicians. Because pulling the cocking ring required significant manual force to overcome the simultaneous resistance of both driver springs, he designed an external integrated cocking mechanism that energized the two springs sequentially, thereby requiring less force than did the simultaneous cocking mechanism of the second generation gun. The third generation gun also provided for separate rearward movement of the needles after the biopsy sample was taken, thereby facilitating removal of the tissue from the stylet. Radiplast applied for a United States patent on the third generation gun on November 14, 1988, naming Dan Åkerfeldt as inventor. The patent issued in 1990 and is the '308 patent in suit.

VALIDITY OF THE '056 REISSUE PATENT

Bard charged M3 Systems with infringement of claims 9-12 and 21-23 of the '056 patent. M3 had the burden of establishing invalidity by clear and convincing evidence at trial. Carella v. Starlight Archery, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1986). On review, the appellate court must "decide for ourselves whether reasonable jurors viewing the evidence as a whole could have found the facts needed to support the verdict in light of the applicable law." Lemelson v. General Mills, Inc., 968 F.2d 1202, 1207, 23 USPQ 1284, 1288 (Fed. Cir. 1992). The appellant must establish that the jury's actual or inferred factual findings were not supported by substantial evidence, or that the found or inferred facts were not sufficient to support the conclusion, or that the law was incorrectly applied. See, e.g., Applied Med. Resources Corp. v. United States Surgical Corp., 147 F.3d 1374, 1376, 47 USPQ2d 1289, 1290 (Fed. Cir. 1998); D.M.I., Inc. v. Deere & Co., 802 F.2d 421, 425, 231 USPQ2d 276, 278 (Fed. Cir. 1986).

When a claim or defense can not be maintained or defeated without a favorable finding on a material issue, and there is not substantial evidence supporting that finding, the verdict can not stand and the court must render judgment as a matter of law. See Fed. R. Civ. P. 50; Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986); see generally Markman v. Westview Instruments, Inc., 52 F.3d 967, 975, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995) (in banc), aff'd, 517 U.S. 370, 38 USPQ2d 1461 (1996). The appellate court must determine whether on the evidence of record a jury might properly have returned a verdict in the non-movant's favor when the correct legal standard is applied. If not, the movant was entitled to have

the question removed from the jury and decided as a matter of law.

We apply these principles to each of the grounds on which the jury rendered verdicts of invalidity of the asserted '056 claims. We direct our discussion of validity primarily to claim 21, for the claim is representative and M3 Systems' expert witnesses admitted infringement of claim 21 by M3's original ACN needles:

> **21.** A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:
>
> a hollow first needle having proximal and distal ends;
>
> a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;
>
> a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing; and
>
> a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for longitudinal motion both toward and away from said forward end of said housing.

A. Anticipation

To meet the requirements of patentability a device must be new; that is, it must not have been previously known. Section 102(a) requires that the subject matter was not published anywhere, or known or used by others in the United States, before its invention by the patentee.[2] An invention that does not meet the requirements of novelty in section 102(a) is said to be "anticipated."

When the defense of lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device. Shearing v. Iolab Corp., 975 F.2d 1541, 1544-45, 24 USPQ2d 1133, 1136 (Fed. Cir. 1992); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984). The jury found that all of the claims at issue were "fully anticipated by a single prior art reference." Bard states that no reference described the new biopsy needle assembly of the '056 patent, and that the closest prior art, which all agree is the Travenol Tru-Cut needle assembly, differs in material ways. M3 Systems states that the Tru-Cut (or a publication describing the Tru-Cut) anticipated the claimed needle assembly because the '056 claims, correctly construed, read on the Tru-Cut.

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[2] **§102.** A person shall be entitled to a patent unless—
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. . . .

The district court declined to construe all of the claim terms that were placed in dispute, instructing the jury that "words in a claim are to be given their ordinary and accustomed meaning, unless it appears that the inventor intended to use them differently. . . . You may use the specification to interpret what the patentee meant by a word or phrase in a claim." The record shows that the court defined some terms and the parties explained their views to the jury. This procedure was not incorrect at the time this case was tried—for as the court observed, the question of the relative roles of judge and jury was then before the Supreme Court—and does not of itself warrant a new trial. On appellate review, however, we apply the principles of Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56, 46 USPQ2d 1169, 1172-75 (Fed. Cir. 1998) (in banc), and determine whether on the correct claim construction the jury verdict can stand. See United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568, 41 USPQ2d 1225, 1236 (Fed. Cir.) (reviewing whether the verdict reached was in accordance with correct claim construction), cert. denied, 118 S. Ct. 369 (1997).

1. The Term "Freely Slidable"

M3 Systems contends that the claim term "freely slidable" does not distinguish the '056 claims from the Tru-Cut needle assembly. The term "freely slidable" appears in the following clause:

> a second needle extending through said hollow first needle and freely slidable therewithin . . . .

Bard argues that the court should have construed "freely slidable" for the jury, and that correctly construed this term means that the needle slides freely in either direction. M3 responds that Bard improperly seeks to insert the limitation

"totally" into the definition of "freely slidable" and that, correctly construed, "freely slidable" requires only sliding freely in the forward direction. M3 states that since the Tru-Cut is freely slidable in the forward direction, the claim reads on the prior art and is invalid for anticipation.

M3 Systems' proposed claim construction is not correct, and could not have reasonably been adopted. The specification leaves no uncertainty that the '056 needles are freely slidable in both directions, for that is a purpose of the new '056 needle structure. M3's proposed interpretation is unsupported by, and indeed is contrary to, the specification. See Slimfold Mfg. Co. v. Kinkead Indus., Inc., 810 F.2d 1113, 1116, 1 USPQ2d 1563, 1566 (Fed. Cir. 1987) (claims are not interpreted "in a vacuum," but are read and understood in light of the specification of which they are a part). The jury's finding of anticipation can not be sustained if grounded on M3's interpretation of "freely slidable," for it was not disputed that the prior art Tru-Cut needles can not slide in both directions.

2. The "Housing"

M3 Systems argues that the preamble of the '056 claims refers only to the "housing" of the tissue sampling device, and that the lack of any preamble reference to an external automatic cocking mechanism invalidates the claims by anticipation because they fail to distinguish the gun of the preamble from the prior art first generation gun.

M3 Systems has incorrectly construed the claim preamble. A preamble may serve a variety of purposes, depending on its content. It may limit the scope of the claim, for example when patentability depends on limitations stated in the preamble, as in In re Stencel, 828 F.2d 751, 754, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987),

or when the preamble contributes to the definition of the claimed invention, as in Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). In this case, however, the preamble simply states the intended use or purpose of the invention, as in Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 868, 228 USPQ 90, 94 (Fed. Cir. 1985). Such a preamble usually does not limit the scope of the claim unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly. In Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 880, 20 USPQ2d 1045, 1053 (Fed. Cir. 1991), for example, the preamble described a "reference point" that provided guidance in understanding and construing the claim.

In the case at bar, the preamble of claim 21 recites the portion and structure of the gun housing into which the needles fit, and provides reference points in the gun that aid in defining the needles as set forth in the body of the claim. M3 Systems is incorrect in stating that the preamble must contain details of the integrated mechanical cocking structure, for the gun structure is not part of the separate claims to the needles. The question of anticipation of the '056 claims relates to the needles, not the gun. To the extent that the jury verdicts of anticipation may have been based on M3's incorrect construction of the preamble, they can not be sustained. On the correct construction of the preamble, it contributes no basis of invalidity on the ground of anticipation.

3. The On-Sale Bar and "Anticipation"

M3 Systems defends these anticipation verdicts by arguing that the asserted claims are anticipated because they are subject to an on-sale bar. Although 35 U.S.C.

§102(b) provides that an inventor's sales or offers of sale more than one year before the patent filing date may bar the grant of a valid patent,[3] the on-sale bar is an independent ground of invalidity based on the inventor's delay in entering into the patent system. Although the on-sale bar can arise from one's own invention, "anticipation" does not arise from sale of one's own invention. We discuss the on-sale issue post; however, this aspect is unrelated to the "anticipation" verdicts, was not part of the jury instruction on that issue, and is not based on correct law.

Conclusion

In sum, M3 Systems directs us to no prior art or prior knowledge or use by others that constitutes substantial evidence of anticipation of the needles claimed in the '056 patent. M3's witnesses conceded that the '056 needles differ from the Tru-Cut in the flange structure for coupling to the gun for movement both toward and away from the housing, a structure that limits all claims, as well as in the additional limitation in claims 10 and 12 of a slit in the stylet head flange. It is not disputed that the Tru-Cut needle assembly lacks these elements. In view of these admitted differences between the '056 needles and the prior art, differences unambiguously stated in the '056 claims, the verdicts of anticipation are unsupported by substantial evidence. The judgment of invalidity on this ground is reversed.

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[3] **§102** A person shall be entitled to a patent unless—
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, . . .

B. Obviousness

Invalidity based on obviousness is a question of law based on underlying facts. See Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966); Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed. Cir. 1987). The relevant facts relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. Graham, 383 U.S. at 17, 148 USPQ at 467; see Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750-51 (Fed. Cir. 1991).

The ultimate determination of obviousness vel non is a legal conclusion. See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985). When a patent describes a new mechanical device that can be viewed as a new combination or arrangement of mechanical components, the legal conclusion of obviousness requires that there be some suggestion, motivation, or teaching in the prior art whereby the person of ordinary skill would have selected the components that the inventor selected and used them to make the new device. See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072, 20 USPQ2d 1377, 1379 (Fed. Cir. 1993) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination."); Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990) (it is insufficient that prior art shows similar

components, unless it also contains some teaching, suggestion, or incentive for arriving at the claimed structure). We review a jury verdict of obviousness to determine whether substantial evidence supports the factual findings predicate to the legal conclusion of obviousness and whether such findings can support the verdict, with appropriate consideration of the presumption of validity and the requirement that obviousness be proved by clear and convincing evidence; factual inferences are drawn and credibility determinations are accepted in favor of the verdict winner. See Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1480, 44 USPQ2d 1181, 1183-84 (Fed. Cir. 1997); Structural Rubber Prod. Co. v. Park Rubber Co., 749 F.2d 707, 718-19, 223 USPQ 1264, 1273 (Fed. Cir. 1984).

M3 Systems argued at trial that the patented needle assembly would have been obvious in light of the Tru-Cut needle assembly, and that the only differences arose from obvious adaptations to accommodate the new gun design and to provide the desired reverse movement of the needles. No other prior art was presented. The invention that was made, however, does not make itself obvious; that suggestion or teaching must come from the prior art. See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051-52, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988) (it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (it is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor); Fromsom v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985) (the prior

art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

No prior art provided a teaching or suggestion or motivation that a needle assembly should be made with the structure shown and claimed in the '056 patent. Absent this essential evidentiary component of an obviousness holding, as a matter of law the verdicts of invalidity on that ground can not stand. Consequently, the judgment of invalidity based on obviousness is reversed.

C. Inventorship

The jury rendered special verdicts of invalidity of the asserted '056 claims on the ground of incorrect inventorship. Inventorship is a question of law, applied to relevant facts. Findings of relevant fact are reviewed on the standard appropriate to the trier of fact, in this case for substantial evidence. See Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980, 41 USPQ2d 1782, 1786 (Fed. Cir.), cert. denied, 117 S. Ct. 2459 (1997). The application of law to the found or admitted facts is reviewed on appeal without deference to the trier of fact. See Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1460, 45 USPQ2d 1545, 1547 (Fed. Cir. 1998); Sewall v. Walters, 21 F.3d 411, 415, 30 USPQ2d 1356, 1358 (Fed. Cir. 1994).

The "inventor," in patent law, is the person or persons who conceived the patented invention. Collar Co. v. Van Dusen, 90 U.S. (23 Wall.) 530, 563-64 (1874); Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1227-28, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) ("Conception is the touchstone of inventorship.") Thus facts relevant to inventorship are those showing the conception of the invention, for others may provide

services in perfecting the invention conceived by another without becoming an "inventor" by operation of law. Id.; Agawarm Co. v. Jordan, 74 U.S. (7 Wall.) 583, 602-04 (1868); Hess, 106 F.3d at 980-81, 41 USPQ2d at 1786-87. As explained in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 785 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "an inventor may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."

An assertion of incorrect inventorship must be based on facts proved by clear and convincing, corroborated evidence. Hess, 106 F.3d at 980, 41 USPQ2d at 1786. The difficulty of determining legal inventorship has been recognized, see Jamesbury Corp. v. United States, 518 F.2d 1384, 1396, 183 USPQ 484, 489 (Ct. Cl. 1975) (inventorship is one of the most difficult issues in American patent law) and, to avoid inadvertent invalidity, 35 U.S.C. §256 permits correction of the designated inventorship of a patent when an error was made without deceptive intent:

> **§256** Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

See Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1556, 43 USPQ2d 1321, 1325 (Fed. Cir. 1997) (error in inventorship may be corrected at any time if no deceptive intent).

The '154 patent as filed in the United States had named Dr. Lindgren as sole inventor. In the course of the reissue proceeding Dr. Lindgren filed a petition in the PTO to add Dan Åkerfeldt as a joint inventor. Lindgren and Åkerfeldt each filed declarations explaining their roles in the invention and declaring that the omission in naming Åkerfeldt was due to differences between United States and Swedish patent law, and was not done with intent to deceive.

M3 Systems challenged the joint inventorship of Lindgren and Åkerfeldt, and also stated that neither one was an inventor of the '056 patent's needles, but that Alan Taylor, President of Hart Enterprises, the company Radiplast retained to manufacture its new needles in the United States, was the sole inventor. Although Mr. Taylor did not appear at the trial, he stated in a deposition that he was not an inventor, but that he suggested the slot in the stylet flange to cooperate with a guide pin in the gun and prevent rotation of the needle. He said he sketched his design for Mr. Engström, although such a sketch was not produced. M3 states that Mr. Taylor gave written notice of his claim in 1990, before the reissue application was filed, but the record citations in M3's brief do not direct us to such notice.

It has long been the rule that one who asserts "inventor" status must provide clear and convincing evidence of supporting facts, including corroborating evidence. See Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1371, 47 USPQ2d 1363, 1366 (Fed. Cir. 1998) (illustrating the historical distrust of uncorroborated oral testimony of prior invention and citing the "rule of reason" analysis of corroborating evidence in Price v. Symsyk, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993)). At the trial Mr. Engström disputed

Mr. Taylor's statements, and the earliest depiction introduced of the flange with a slot was a Swedish document.

Alternatively, M3 Systems points to the design patents that were filed in the name of Åkerfeldt alone, as establishing that Dr. Lindgren was not a joint inventor of the needles with Åkerfeldt. Bard replies, and there is no dispute, that the design patents showed specific hub designs not shown in the utility patent. Whether Åkerfeldt was the sole inventor of specific hub designs does not negate his joint inventorship of the needles of the '056 patent, which are depicted and claimed broadly. Bard also stresses that if indeed there were error in inventorship, such errors are correctable and do not invalidate the patent absent deceptive intent. To invalidate a patent based on incorrect inventorship it must be shown -not only that the inventorship was incorrect, but that correction is unavailable under section 256:

> **§256[¶2]** The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. . . .

Although M3 contends that deceptive intent can be inferred from the omission of Taylor as an inventor, precedent requires that one who claims a share of inventorship must establish that right by clear and convincing evidence. Ethicon, 135 F.3d at 1465-66, 45 USPQ2d at 1552; Hess, 106 F.3d at 980, 41 USPQ2d at 1785-86. Since such evidence was absent, the judgment of invalidity based on incorrect inventorship can not stand, and is reversed.

D. Violation of Reissue Requirements

The jury also found by special verdicts that the asserted '056 claims were invalid on the ground that the reissue requirements were not met. M3 Systems explains in its brief that the jury found that "any purported error in the '154 patent could not be corrected by reissue," explaining that the errors were the error in inventorship and the error in failing to claim the needles in the original '154 patent.

With respect to the argument that the correction of inventorship was improperly made by reissue, we have been directed to no legal or procedural error, for the prosecution history clearly shows that the error in inventorship was described in the reissue application and corrected by appropriate petition, filed and processed while the reissue application was pending. A petition to correct inventorship, 37 C.F.R. §1.324 (1991), may be filed during reissue proceedings. The error in inventorship was corrected before the reissue patent was granted, and thus the reissued patent names Lindgren and Åkerfeldt as the inventors. This procedure can not have provided ground for a reasonable jury's verdicts of invalidity based on violation of reissue requirements.

The other aspect that M3 Systems argued was not amenable to correction by reissue was the addition of claims to the needles *per se*. That argument incorrectly states the reissue law, for a primary purpose of the reissue statute is to enable the addition of claims to subject matter not claimed in the original patent. See Scripps Clinic & Res. Found'n v. Genentech, Inc., 927 F.2d 1565, 1575, 18 USPQ2d 1001, 1009 (Fed. Cir. 1991) (purpose of reissue statute is to avoid forfeiture of substantive rights due to erroneously claiming less than entitled, through error

without intent to deceive); In re Wilder, 736 F.2d 1516, 1518-19, 222 USPQ 369, 371-72 (Fed. Cir. 1984) (purpose of reissue is to correct errors such as misunderstanding scope of the invention and claiming less than that to which the inventor was entitled).

M3 Systems states that since the needles were not claimed originally they were not "intended" to be claimed, and that absence of such intent is not an error correctable by reissue. That too is an incorrect statement of the law. An inventor's failure to appreciate the scope of an invention at the time of the original patent grant, and thus an initial intent not to claim the omitted subject matter, is a remediable error. See In re Amos, 953 F.2d 613, 619, 21 USPQ2d 1271, 1276 (Fed. Cir. 1991) (reissue application not subject to rejection for failure to demonstrate initial intent to claim, when subject matter of reissue claims satisfies §112 requirements); In re Weiler, 790 F.2d 1576, 1581, 229 USPQ 673, 676-77 (Fed. Cir. 1986) ("intent to claim" is shorthand for a means of measuring whether required error is present); In re Hounsfield, 699 F.2d 1320, 1322, 216 USPQ 1045, 1048 (Fed. Cir. 1983) (lack of "intent to claim" is only one factor to be considered).

M3 Systems also argues that the error in failing to claim the needles should have been corrected sooner. The reissue statute sets a two-year time limit for filing a broadening reissue application. This requirement was met. See 35 U.S.C. §251; In re Graff, 111 F.3d 874, 877, 42 USPQ2d 1471, 1473-74 (Fed. Cir. 1997) (broadened claims must be filed within two years); see also 37 C.F.R. §1.175 (1991). There is no requirement that a patentee act earlier than later during the two-year window established by statute.

M3 Systems has stated no basis in fact or law for its assertion that any reissue procedure was violated. The verdicts of invalidity on this ground are unsupported in law, and judgment based thereon is reversed.

E. The On-Sale Issue[4]

The jury also found that the aserted '056 claims were invalid on the ground that the new needle assembly had been "patented or published or in public use or on sale" in the United States more than one year before the filing date of the '154 patent application in the United States. See 35 U.S.C. §102(b), supra note 3. Since that filing date was July 30, 1986, the critical date for bar purposes is July 30, 1985.

Although the special verdicts did not distinguish among the statutory grounds of patented or published or in public use or on sale, the major focus at trial and on appeal is the issue of on sale. While M3 Systems also argued that there was a bar based on publication and public use, the only evidence referred to relates to the first generation gun and the Tru-Cut needles, which are acknowledged prior art and are not claimed in the patents in suit. M3's argument at trial that these prior art devices were also a bar to the '056 claims under section 102(b) is not pressed on appeal.

The '154 and '056 patents are directed to the second generation gun and new needles. Before the critical date, indeed before the development of the second generation gun and new needles had been completed, Radiplast was

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[4] This section is the dissenting opinion of Judge Newman. The court affirms the judgment of invalidity for violation of the on-sale bar, in separate opinions of Chief Judge Mayer and Judge Bryson.

engaged in a variety of activities directed to the United States market. These activities included demonstrating and promoting the first generation gun with the Tru-Cut needles, pursuing arrangements for clinical trials for the second generation gun and new needles through collaboration with a potential United States distributor, applying for FDA approval, arranging for manufacture of the needles in the United States, and related activities directed to commercial goals. Although Radiplast's final needle design was developed after the critical date, the issue at trial was the effect of these prior activities under the law of section 102(b).

Federal Circuit precedent on the on-sale bar requires consideration by the court of the totality of the circumstances in light of the various policies that underlie the bar. Precedent explains that "while a wide variety of factors may influence the on sale determination, no single one controls the application of section 102(b), for the ultimate conclusion depends on the totality of the circumstances." Ferag AG v. Quipp, Inc., 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995); see Envirotech Corp. v. Westech Eng'g Inc., 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990).

Although a few cases have recognized the advantages of a bright line rule that would be applicable in all cases, that is, a defining event whereby an inventor will know when the bar will accrue, generally the court has undertaken to weigh the particular facts of the commercial activity against the particular policy considerations that apply to the situation, giving effect to the principle that "the policies or purposes underlying the on sale bar, in effect, define it." RCA Corp. v. Data General Corp., 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). Thus, in general, "this court has been careful to avoid

erecting rigid standards for 102(b)." Western Marine Elecs., Inc. v. Furuno Elec. Co., 764 F.2d 840, 844, 226 USPQ 334, 337 (Fed. Cir. 1985); see Petrolite Corp. v. Baker Hughes, Inc., 96 F.3d 1423, 1425, 40 USPQ2d 1201, 1203 (Fed. Cir. 1996) ("This court has emphasized that the totality of the circumstances must be considered in determining whether a particular event creates an on-sale or public use bar." (quoting U.S. Environmental Prods., Inc. v. Westall, 911 F.2d 713, 716, 15 USPQ2d 1898, 1901 (Fed. Cir. 1990))).

The determination of whether a product was on sale in terms of section 102(b) is a question of law. See Micro Chem., Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1544, 41 USPQ2d 1238, 1243-44 (Fed. Cir. 1997) (discussing precedent and applying the totality of the circumstances standard as a matter of law); KeyStone Retaining Wall Sys., Inc. v. Westrock, Inc., 997 F.2d 1444, 1451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993) (explaining relevant factual inquiries); Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1562-64, 4 USPQ2d 1210, 1213-14 (Fed. Cir. 1987) (discussing various factors to be weighed in context of experimental testing by third persons).

The various policy considerations include the policy of providing a limited but normally sufficient time (one-year) for the inventor to test the commercial reception of the invention before deciding whether it warrants patenting; the policy of limiting the period during which the patentee may delay entering into the patent system for the purpose of deferring the end of the period of patent-based exclusivity; the policy favoring prompt public disclosure of inventions through the patent system; and the policy of recognizing the practical consideration whereby the value of an invention may not be known until it is publicly tested.

Depending on the dominant policy considerations in the particular case, applied to the factual circumstances of that case, the Federal Circuit has reached a variety of conclusions as to when the on-sale bar arose. The court's precedent illustrates rulings ranging from the requirement that the patented product was produced and available commercially before the on-sale bar started to accrue, to rulings that the bar was triggered before the invention had been completed.

Before the critical date for the '056 patent, July 30, 1985, three sets of events were explored at trial. The facts are not in dispute; the question is whether as a matter of law, the on-sale bar arose in these circumstances.

1. The Clinical Trials

The clinical trials were arranged by American Pharmaseal, Radiplast's potential distributor in the United States, and were conducted in August and September 1985 (after the critical date) using the second generation guns and new needles. In January 1985 Thomas Engström of Radiplast had quoted to Pharmaseal the price for 12 guns and 500 needles for use in the trials. Pharmaseal later that spring requested 10 guns and 250 needles, for which Radiplast sent an invoice in June 1985. Mr. Engström testified that this payment was to defray some of Radiplast's costs in providing these devices, and was so understood. It was not disputed that the transaction produced no profit for Radiplast.

M3 Systems asserts that Radiplast sold the 10 guns and 250 needles to Pharmaseal, pointing out that a standard sales invoice was used. Bard replies that this was a transaction between collaborators, not a commercial sale and not a sale for commercial distribution. Dr. Lindgren

testified that he visited the four United States hospitals that were testing the device (after the critical date), to explain its use and to see how it worked in different tissues, operated by different doctors. Bard stresses that the devices were not sold, that all but one were returned by the hospitals after the clinical trials, and unused needles were destroyed.

Generally cost defrayal arrangements between collaborators are not deemed to be invalidating sales, nor are payments for use substantially for test purposes. See In re Mahurkar, 71 F.3d 1573, 1577, 37 USPQ2d 1138, 1142 (Fed. Cir. 1995) (actual sale of two prototype catheters "did not place the invention in the public domain or lead the public to believe that the device was freely available"); Ethicon, Inc. v. United States Surgical Corp., 762 F. Supp. 480, 506-07, 19 USPQ2d 1721, 1740 (D. Conn. 1991) (clinical tests by surgeon not a public use under §102(b)), aff'd, 765 F.2d 1062 (Fed. Cir. 1992) (Table); Baker Oil Tools, 828 F.2d at 1564, 4 USPQ2d at 1214 (discussing factors in deciding whether the purpose of testing was primarily experimental). In its submissions to the PTO during the reissue proceeding Radiplast characterized the transaction concerning the 10 guns and 250 needles as for experimental purposes.

It is not disputed that the sole purpose of this transaction was to make the devices available to the four selected hospitals for a limited test period. Radiplast's arrangement with Pharmaseal for payment or defrayal of the cost of providing the devices was not a sale or offer of sale as contemplated by section 102(b). It contravenes none of the policies underlying the on sale bar for Radiplast to have recouped these costs. Upon considering the totality of the circumstances, I conclude that an on-sale bar did not

arise based on this transaction between Radiplast and Pharmaseal in connection with the clinical trials.

2. The Bulk Price Quotation

In January 1985 Radiplast quoted to Pharmaseal prices for various bulk quantities of up to 50,000 needles. At that time the new needles were still being modified, and the record shows that design changes were made well after January 1985. Mr. Engström of Radiplast testified that the quotation was information for a potential distributor, in the event that Pharmaseal accepted that role (it did not). The bulk price quotations were in a telex that stated, "This is to give you an indication of the price levels. We have to meet and discuss more in detail all things related with the marketing of our biopsy instrument in US." It was not disputed that the quotation was for modified needles, and that both parties understood that the modified needles were not yet available.

M3 Systems argues that since the first generation device had been shown to operate for its intended purpose using Tru-Cut needles, the inventor had already convinced himself that he had a satisfactory product that he wished to commercialize in the United States, and thus that the bulk price quotation, even if for needles not yet developed, was an on-sale event. M3 stresses that the price quoted for bulk quantities included a profit for Radiplast, unlike the price for the clinical trial quantities.

Quotation of a sales price to a potential distributor of a product that is not available for sale and distribution does not of itself establish an on-sale bar. See Continental Can, 948 F.2d at 1270, 20 USPQ2d at 1750 (price terms set between collaborators in joint research not an on-sale bar); Shatterproof Glass, 758 F.2d at 622, 225 USPQ at 639

("clear weight of authority is that a bare offer to sell does not ipso facto satisfy the 'on sale' bar"). A primary policy served by the on-sale bar is to provide time for an inventor to determine the reception of his invention in the marketplace before entering into the patent system, while the one-year limit prevents undue lengthening of the period of exclusivity. The policy is served when cognizance is taken of whether the invention is ready for commercial use at the time that customer contacts are made. Although exceptions have arisen on particular facts, normally the on-sale bar does not accrue based on customer contacts made while the product is still being developed or tested. See KeyStone, 997 F.2d at 1451, 27 USPQ2d at 1303 (on-sale bar "requires that the device asserted to be on sale was operable"); Seal-Flex Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1322, 40 USPQ2d 1450, 1452 (Fed. Cir. 1996) (invention not completed if it required testing under conditions of actual use).

In this case, the circumstances of the incomplete stage of development of the second generation gun and proposed new needles at the time of this price quotation, the potential but not established distributor relationship underlying this quotation, the planned clinical collaboration, and the non-existence of a completed final product, negate the accrual of an on-sale bar from this price quotation. It seems clear that neither Radiplast nor Pharmaseal expected that this bulk price quotation would be followed by the placement of an order. To satisfy the on-sale requirement of section 102(b) there must be more than an informational exchange of price information, when there is no reasonable contemplation that the quotation will be followed by purchase and sale as a commercial transaction.

I conclude that the verdicts of invalidity based on the on-sale bar can not be supported by this bulk price quotation.

3. The Correspondence With Dr. Phelps

The third event raised by M3 Systems occurred in November 1984. Mr. Engström of Radiplast responded to a letter written in September 1984 by Dr. Phelps, a physician in Alabama, who had seen a demonstration and brochure for the first generation device and wrote to Sweden for information. Engström wrote back that he hoped to start marketing a second generation device and new needles in the United States in early 1985, and that if Dr. Phelps did not wish to wait until United States distribution was arranged he could order directly from Sweden; the letter quoted prices for a gun and needles. No further correspondence ensued. Dr. Phelps testified that he expected that had he sent an order it would have been filled, and that he knew nothing about the difference between "generations." Mr. Engström testified that neither the new needles nor the completed second generation gun was available when he answered Dr. Phelps.

An offer of sale originating in a foreign country, directed to a consumer in the United States, can establish an on-sale bar as to what was offered. In re Caveney, 761 F.2d 671, 676-77, 226 USPQ 1, 4 (Fed. Cir. 1985). The demonstration and brochure that led to Dr. Phelps' inquiry were of the first generation device, which used Tru-Cut needles. Although the details of Radiplast's product changes were not explained to Dr. Phelps it was undisputed that an order, if placed, could not have been filled at that time with the second generation gun and needles. Cf. King Instrument Corp. v. Otari Corp., 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985)

(finding it significant that purchaser could discern that it was the later-patented invention being offered for sale).

At the time of Mr. Engström's letter the second generation device and needles were in an early development stage. Although Dr. Phelps was not told the details of these developments, this correspondence did not raise an on-sale bar to a product not yet developed. As held in Robotic Vision Sys. Inc. v. View Eng'g. Inc., 112 F.3d 1163, 1167-68, 42 USPQ2d 1619, 1623 (Fed. Cir. 1997), "subsequent completion of an invention after the critical date does not relate back to the date of an earlier alleged offer of sale." See also Micro Chem., 103 F.3d at 1544-45, 41 USPQ2d at 1243 (no on-sale bar when invention not completed at time of offer, only prototype and sketch of proposed configuration); Shatterproof Glass, 758 F.2d at 622, 225 USPQ at 639 (not an on-sale bar to solicit orders before invention completed); cf. Pfaff v. Wells Elecs., Inc., 124 F.3d 1429, 43 USPQ2d 1928 (Fed. Cir. 1997), cert. granted, 118 S. Ct. 1183 (1998) (No. 97-1130) (although invention not reduced to practice because no physical embodiment had been made, the firm purchase order and delivery date accrued the on-sale bar) (citing UMC Elecs. Co. v. United States, 816 F.2d 647, 2 USPQ2d 1465 (Fed. Cir. 1987)). On the totality of the circumstances, considering the relevant policies and the undisputed facts, I conclude that this letter to Dr. Phelps, written in response to an inquiry about the first generation device, which resulted from a brochure on the first generation device, stating the price for the second generation device and needles before they were fully developed and before they were available, did not trigger the on-sale bar.

Upon de novo review of the totality of the circumstances, with due consideration to the applicable

policies, the undisputed facts, and drawing factual inferences in favor of the verdicts, I conclude that the verdicts of invalidity based on a section 102(b) bar are incorrect; I would reverse the judgment on that ground.[5]

II

INFRINGEMENT OF THE '056 PATENT

In view of the majority's affirmance of the judgment of invalidity, we do not reach the issue of infringement of the '056 patent. That judgment is vacated.

III

VALIDITY OF THE '308 PATENT

The '308 patent is directed to the third generation gun. The jury found the asserted claims of the '308 patent not infringed, and invalid or unenforceable on the grounds of anticipation, obviousness, and insufficient supporting

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[5] The three different views in the three opinions of this panel on the on-sale issue point up the need for a more certain law than today exists. Inventors and those who commercialize inventions should reasonably know when the on-sale bar starts to accrue, instead of awaiting litigation-borne *post hoc* judicial evaluations of the totality of the circumstances, varying with the nature of the invention, the nature of the customer contact, and the judicial weight given to the conflicting policy interests.

I favor, as simple and fair, the bright line rule that for the §102(b) on-sale bar to accrue the invention must exist in commercial form when the offer of sale is made. This rule would implement the dominant policy of providing a one-year grace period for determining the performance of the product in the marketplace.

description, as well as for fraud, misuse, and violation of antitrust law, as discussed in Parts V-VII, post.

Claims 15 and 16 were at issue, with emphasis added to show the claim terms whose construction is relevant to the issues of patent validity or infringement:

> **15.** A tissue sampling device comprising:
>
> a guide sleeve having front and rear guide sleeve ends and defining a longitudinal axis extending between said front and rear guide sleeve ends, said front guide sleeve end having an opening therethrough;
>
> a hollow first needle positioned within said guide sleeve and extendable from said opening, said hollow first needle being moveable along said axis;
>
> a second needle extending through said hollow first needle and moveable along said axis, said second needle having a tip which is extendable from said hollow first needle and said opening, and said second needle further including a tissue sample receiving recess;
>
> a first needle head coupled to said hollow first needle and mounted within said guide sleeve for movement along said axis to move said hollow first needle along said axis;
>
> a second needle head coupled to said second needle and mounted within said guide sleeve for movement along said axis to move said second needle along said axis;
>
> a first spring disposed within said guide sleeve and operatively associated with said second needle head, said first spring being capable of being

placed into an energized mode to store energy, and said first spring being releasable from said energized mode to propel said second needle head along said axis towards said opening, such that said tip of said second needle is extended from said hollow first needle, whereby a tissue sample can be captured within said recess;

a second spring positioned within said guide sleeve and operatively associated with said first needle head, said second spring being capable of being placed into an energized mode to store energy, and said second spring being releasable from said energized mode to propel said first needle head along said axis towards said opening, said hollow first needle being extended from said opening such that said recess of said second needle is enclosed by said hollow first needle;

a first latch means selectively releasable from outside said guide sleeve for releasably holding said first spring in said energized mode;

a second latch means for releasably holding said second spring in said energized mode, said second latch means being releasable in response to and subsequent to release of said first spring; and

sequential energizing means operative to move said first needle head along said axis towards said rear guide sleeve and to cause said second latch means to hold said second spring in said energized mode, and subsequently to move said second needle head along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode.

Claim 16 is the same as claim 15 except for the last clause, which includes the selective retraction of the stylet to expose the tissue sample:

> **16.** . . . energizing means operative to move said first needle head and said second needle head along said axis towards said rear guide sleeve and to cause said first latch means to hold said first spring in said energized mode and to cause said second latch means to hold said second spring in said energized mode, said energizing means being selectively operative to move said first needle head but not said second needle head towards said rear guide sleeve end, whereby said hollow first needle is selectively retractable to expose said tissue sample receiving means in said second needle.

A. Support by the Written Description

The jury found claims 15 and 16 "not supported by the description contained in the specification." M3 Systems explains that the issue was the meaning of the claim terms "sequential energizing" and "energizing means." The district court had permitted the jury to resolve this disputed issue of claim construction. On this appeal we give de novo review to the issues relevant to the construction and interpretation of the claims. See Cybor, 138 F.3d at 1454-56, 46 USPQ2d at 1172-75.

M3 Systems states that "sequential" should be construed, and was construed by the jury, to permit no overlap of needle movement during the energizing step. M3 states that since the patent shows that the second needle can start to move before the first needle has completed its movement, the written description does not support the claims. M3 states, as it did at trial, that since the

specification does not describe how to obtain elimination of all overlap of needle movement, the claims are not supported by the written description and are invalid.

Bard agrees that the specification shows a slight overlap in the movement of the needles, whereby the second needle starts to move just before the first needle has completed its movement and the first spring latches. Thus, Bard contends, correct interpretation of the claims allows for this slight overlap in needle movement. Bard states that it is incorrect to construe the claims contrary to the specification, and then to hold the claims invalid because they are contrary to the specification. Bard is of course correct; the claims are construed in accordance with the rest of the specification of which they are a part, and not contrary to it. See Slimfold Mfg., 810 F.2d at 1116, 1 USPQ2d at 1566; SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1125, 227 USPQ 577, 585 (Fed. Cir. 1985) (in banc).

The specification illustrates the sequential energizing of the needles as having some overlap in movement of the needles. The term "sequential" in the claims is in accordance with this description in the specification; no usage or exemplification of the sequential movement requires eliminating all overlap. It is incorrect to construe the claims as barring all overlap, as urged by M3 Systems. On the correct claim construction, no reasonable jury could have found that the claims are not supported by the description in the specification. It is thus apparent that the jury either adopted M3's erroneous claim construction, or incorrectly applied the law governing claim construction to the undisputed facts of the structure described in the specification.

On the correct claim construction the written description is in accordance with and in support of the claims. The judgment of invalidity on this ground is reversed.

B. Anticipation

The jury also found claims 15 and 16 invalid based on anticipation. "Anticipation" requires that the identical invention was already known to others, that is, that the claimed invention is not new. See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1572, 24 USPQ2d 1321, 1332 (Fed. Cir. 1992) ("In order to anticipate, the [reference] must sufficiently describe the claimed invention to have placed the public in possession of it.") M3 Systems argued that anticipation arose on the published PCT application describing the first generation biopsy gun, and on the device itself. It was not disputed, however, that the first generation gun lacks the integrated mechanical energizing structure described and claimed in the '308 patent, and that the PCT application does not show such structure.

M3 Systems' argument was that when the claims are correctly construed they are anticipated. M3 states that on the claim construction reached by the jury in finding claims 15 and 16 unsupported by the written description, whereby the term "sequential" is defined as barring all overlap in needle movement, the structure in the specification is inconsistent with the claims and therefore must be disregarded. M3 argues, as we understand it, that since "energizing means" and "sequential energizing means" are in means-plus-function form, it is appropriate to disregard the structure in the specification that is inconsistent with the claim language, leaving the claimed functions with "no disclosed supporting structure," quoting

from M3's brief. Thus, according to M3, these claim terms are directed only to function, and can be anticipated by any prior art that shows the function of energizing or sequential energizing, without limit to how that function is performed. Thus M3 argues that since the PCT application and the first generation gun are manually sequentially energized, one spring at a time, the jury correctly found anticipation by the first generation gun and the PCT application.

Indeed, the jury verdicts can be understood only if one adopts so tortured a view of the law. As we have discussed, it is incorrect to construe claims contrary to the specification, and it is incorrect to construe terms in means-plus-function form as disembodied from the structure in the specification. M3 Systems' witnesses readily admitted that the integrated mechanized gun described and claimed in the '308 patent is different from the first generation gun and the description of that gun in the PCT application. On the undisputed facts and the correct law, a reasonable jury could not have found the '308 claims anticipated thereby. The judgment of invalidity for anticipation must be reversed.

C. Obviousness

M3 Systems argues that the third generation gun of the '308 patent would have been obvious in view of the PCT application and the first generation gun, in combination with the '154 patent describing the second generation gun. M3 states that the third generation is an obvious combination of elements found in the first and second generations. See discussion, Part I.B. ante, of the law of obviousness. There was no dispute as to the scope and content of this prior art, or as to the elements in the third generation gun that were not in either the first or second generations. The only dispute was the ultimate

question of whether the third generation gun would have been obvious from what had gone before.

M3 Systems contends that for the third generation the inventor simply changed the integrated mechanical cocking mechanism of the second generation gun to accomplish mechanically the sequential cocking that was necessarily done when the first generation gun was manually cocked, one spring at a time. Bard replies that the one-at-a-time cocking of the springs in the first generation, by hand or by miniature crowbar, does not teach or suggest the integrated automatic sequential cocking of the third generation, and that there is no teaching or suggestion in the prior art to make such a combination, or of the structure having the improved ease of handling of the third generation gun. Bard also points to the other new structural features of the third generation whereby the needles can be retracted separately after tissue sampling.

The ultimate question is whether, from the evidence of the prior art and the knowledge generally available to one of ordinary skill in the relevant art, there was in the prior art an appropriate teaching, suggestion, or motivation to combine components in the way that was done by the inventor. See, e.g., Uniroyal, 837 F.2d at 1050, 5 USPQ2d at 1438; ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). The ultimate determination of obviousness is a legal conclusion. When this legal conclusion is drawn by the jury the verdict is reviewed, as discussed in Part I.B, to determine whether substantial evidence supports the factual findings necessary to support the legal conclusion, with due consideration to the presumption of validity and the standard of proof.

Bard points out that its rotating sleeve mechanism for sequential energizing is a marked distinction from its earlier devices, even were the concept of sequential energizing deemed to be derivable from the manual operation of the first generation. M3 Systems does not cite any reference suggesting the structure employed in the third generation gun, or any suggestion of mechanical sequential energizing, or indeed the other features of the third generation. Those contributions came from the inventor, not the prior art. See Uniroyal, 837 F.2d at 1050, 5 USPQ2d at 1438. We have been directed to no teaching or suggestion of this combination in the descriptions of the first and second generation guns, viewed separately or together. Thus the verdicts of invalidity on the ground of obviousness are without essential factual support, and can not stand.

IV

INFRINGEMENT OF THE '308 PATENT

The jury found that M3 Systems did not infringe claims 15 and 16 of the '308 patent. Because the special verdicts discussed in Part III.A (that there is not support for these claims in the written description) require an incorrect claim construction, we have reviewed the verdicts of noninfringement on the correct construction, i.e., that claims 15 and 16 do not require a total absence of overlap in the sequential movement of the needles during energizing. Bard contends that on the correct claim construction the verdicts of noninfringement can not stand. Bard is entitled to a new trial if a jury reasonably could have reached verdicts of infringement upon correct claim construction and correct application of the law of infringement. However, if only one result is supportable in law and on undisputed facts, judgment as a matter of law is

appropriate. See Strattec, 126 F.3d at 1419, 44 USPQ2d at 1036.

On appeal Bard argues only the issue of sequential energizing, asserting literal infringement under section 112 paragraph 6. M3 Systems does not dispute, and indeed emphasizes, that in its ProMag devices there is sequential energizing with a slight overlap in needle movement. However, M3's performance of the function of sequential energizing was not the only disputed issue with respect to infringement. M3 also points out that its device is a box-type biopsy gun and does not contain a "guide sleeve" as required by the claims, and that the M3 ProMag guns use linear tensioning whereas the '308 device performs counter-rotational tensioning, such that the structure used by M3 is not equivalent to that shown in the '308 specification, applying section 112 paragraph 6 to the energizing means of the '308 claims.

M3 Systems states that the '308 patent draws a distinction between box-type biopsy guns such as those made by M3 wherein the housing is merely a container for the device, and guns embodying a mechanism wherein the guide sleeve and a tensioning sleeve interact and serve as part of the cocking mechanism. M3 argued at trial that its housing is independent, whereas in the '308 specification the gun is housed in a two-part structure wherein the inner part is the guide sleeve and the outer part is the tensioning sleeve and rotates about the inner part. These sleeves bear cam surfaces and slots that interact with the flanges on the needle heads and thus serve as part of the cocking mechanism. M3 states that its gun has neither a guide sleeve nor a tensioning sleeve, and that its housing is merely the container for the device, and is unconnected with the cocking mechanism.

Although the claims in suit do not require a tensioning sleeve, see D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574, 225 USPQ 236, 239 (Fed. Cir. 1985) (improper to import limitation from one claim into another claim lacking the limitation), the guide sleeve is described in the specification as "the inner sleeve or guide sleeve." The specification shows and the claims require that the guide sleeve perform a guiding function for the cocking mechanism. Bard does not assert that such a structure is found in the M3 guns. Nor does Bard raise on this appeal any issue of equivalency under the doctrine of equivalents.

At the trial the parties presented evidence on how the patented and accused devices worked, and the court instructed the jury as to the applicable law of infringement of means-plus-function claims. For the energizing means Bard was required to establish, by a preponderance of evidence, that M3 Systems'device embodies the structure described in the '308 specification or an equivalent thereof. 35 U.S.C. §112 ¶6; Valmont Indus., Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 1041-42, 25 USPQ2d 1451, 1453-54 (Fed. Cir. 1993); Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1562-63, 231 USPQ 833, 834-35 (Fed. Cir. 1986). Since the structure of the M3 energizing means is not the same as that described in the '308 specification, the issue was whether the structures are equivalent. See D.M.I., 755 F.2d at 1575, 225 USPQ at 239 ("[T]he sole question is whether the single means in the accused device which performs the function stated in the claim is the same as or an equivalent of the corresponding structure described in the patentee's specification as performing that function.") The determination of infringement under section 112 paragraph 6 is a factual question. In re Hayes Microcomputer Prods. Inc. Patent Litig., 982 F.2d 1527, 1541, 25 USPQ2d 1241,

1251 (Fed. Cir. 1992); Intel Corp. v. United States Int'l Trade Comm'n, 946 F.2d 821, 841, 20 USPQ2d 1161, 1178 (Fed. Cir. 1991); D.M.I., supra.

There was no dispute that the function of sequential energizing is performed in the M3 Systems' guns; the only question was whether the M3 guns employ the same or an equivalent of the structure described in the '308 specification. The accused equivalent structure need not have been known at the time the patented invention was made. See Texas Instruments, 805 F.2d at 1563-64, 231 USPQ at 834-35 ("It is not required that those skilled in the art knew, at the time the patent application was filed, of the asserted equivalent means of performing the claimed functions . . . .")

It was explained at trial that to achieve sequential energizing in the '308 device the outer tensioning sleeve is rotated about the inner guide sleeve; cam surfaces on the interior of the tentioning sleeve push against wings built directly into the needle heads to compress the two springs in sequence, pressing them rearward into the locked position. In contrast, in the M3 Systems device a handle connected through the rear of the housing acts on sleds bearing the needles; M3's device relies on the lever-action of the handle, as opposed to a rotating sleeve, to pull, rather than push, the needle sleds sequentially back toward their respective latches. Bard had argued at trial, in connection with the issue of validity, that the claims "must be interpreted as means-plus-function terms in accordance with Valmont," and cited its "external integrated energizing mechanism that converts rotary motion to linear motion" to distinguish the '308 gun from its own earlier device. Claims must be interpreted the same way for determining infringement as was done to sustain their validity.

A reasonable jury could have found that the structure using rotational tensioning as the energizing means is substantially different from the energizing structure in the M3 Systems guns. Although Bard argues that it suffices for infringement if the energizing is achieved with the slight overlap shown in the '308 patent, that is, if the function of sequential energizing is performed, claims written in the form authorized by section 112 paragraph 6 are limited by the structure described and equivalents of that structure. Performance of the same function does not of itself establish infringement.

Bard directs us to the doctrine of claim differentiation, and argues that it is incorrect to interpret the "sequential energizing means" of claim 15 as limited to the structure in the specification, because other claims, not at issue, specifically state that structure. Bard argues that its claims in suit are broader in that they state only the function of sequential energizing, and that they therefore warrant broader scope than the claims that state a specific energizing structure. However, as we have discussed, claims that are written in the form authorized by section 112 paragraph 6 are by statute limited to the structure described in the specification and equivalents of that structure. As discussed in Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538, 19 USPQ2d 1367, 1371 (Fed. Cir. 1991) a "means-plus-function limitation is not made open-ended by the presence of another claim specifically claiming the disclosed structure which underlies the means clause or an equivalent of that structure."

Applying this law, and based on the absence of a guide sleeve or any counterpart structure, and the differences in the structures of the energizing mechanisms, we conclude that on the correct claim interpretation a

reasonable jury could find that claims 15 and 16 are not infringed. The judgment of noninfringement of the '308 patent is affirmed.

V

FRAUD

M3 Systems charged that Bard had committed both fraud and inequitable conduct in prosecuting the '056 and '308 patents. The jury was not asked to decide the issue of inequitable conduct, which was reserved to the judge and withdrawn by M3 after the favorable verdicts on the question of fraud. The jury found that it had been established by clear and convincing evidence that each of the '056 and the '308 patents had been procured by fraud in the Patent and Trademark Office.

Fraud in the procurement of a patent requires proof of the elements of fraud as developed in the common law: (1) that a false representation of a material fact was made, (2) with the intent to deceive, (3) which induced the deceived party to act in justifiable reliance on the misrepresentation, and (4) which caused injury that would not otherwise have occurred. See Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70, 46 USPQ2d 1097, 1105-06 (Fed. Cir. 1998); Norton v. Curtiss, 433 F.2d 779, 792-94 & n.12, 167 USPQ 532, 543-45 & n.12 (CCPA 1970) (citing W. Prosser, Law of Torts §§100-05 (3d ed. 1964)).

The tort of fraud requires that there was a successful deception, and action taken by the person deceived that would not have otherwise been taken. Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability,

(2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable, and when accompanied by the elements of violation of the Sherman Act, as discussed in Part VI, can incur additional consequences.

To establish fraud for purposes of antitrust violation the defendant "must make a greater showing of scienter and materiality" than when seeking unenforceability based on conduct before the Patent Office. 6 Donald S. Chisum, Chisum on Patents §19.03[6][e] (rel. 47 1993) (citations omitted). In Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177, 147 USPQ 404, 407 (1965) the Court clarified that "knowing and willful" fraud must be shown, and is predicate to potential antitrust violation. As explained in Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 996, 202 USPQ 342, 351 (9th Cir. 1979), "[t]he road to the Patent Office is so tortuous and patent litigation is usually so complex, that 'knowing and willful fraud' as the term is used in Walker can mean no less than *clear, convincing proof of intentional fraud involving affirmative dishonesty*, 'a deliberately planned and carefully executed scheme to defraud * * * the Patent Office.' . . . Patent fraud cases prior to Walker required a rigorous standard of deceit. . . . Walker requires no less." (Emphasis and elisions in original.) The requirements of common law fraud are in contrast with the broader sweep of "inequitable conduct," an equitable conduct defense that may be satisfied when material information is withheld with the intent to deceive the examiner, whether or not the examiner is shown to have relied thereon. See Kingsdown

Med. Consultants v. Hollister, Inc., 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988).

M3 Systems stated that Bard made myriad material misrepresentations in prosecuting the '056 and '308 patents, including the following: the incorrect inventors were named; actual samples of the Tru-Cut needles and the first generation device were not provided to the examiner; the Baxter patent on the Tru-Cut needle and two Lindgren articles on the first generation device were not provided to the examiner; the material submitted to the FDA was not provided to the examiner; the examiner was not told of the co-pending design patents; and the examiner was not provided with all of the evidence on the on-sale issue. Bard responded that there is no substance to any of these assertions; that all material information was presented to the examiner; that there was no intent to deceive the examiner; that the examiner was not deceived; and that the evidence points to good faith in the prosecution of these patents. Good faith is an absolute defense to the charge of common law fraud. See Walker Process, 382 U.S. at 177, 147 USPQ at 407.

M3 Systems argues that any omission in the submissions to the PTO is "necessarily material, because the allowance of the application is the intended natural consequence of that submission." That is not a correct statement of the law. There is no presumption that information not filed by an applicant was material simply because patentability ensued. To establish culpability any omission must be of a fact material to patentability and it must be a deliberate misrepresentation, whether by omission or misstatement, that was intended to and did mislead the examiner into taking favorable action that would not otherwise have been taken. Intent to mislead or to deceive must be proved by clear and convincing

evidence. See Walker Process, supra. Deceptive intent is not inferred simply because information was in existence that was not presented to the examiner; and indeed, it is notable that in the usual course of patent prosecution many choices are made, recognizing the complexity of inventions, the virtually unlimited sources of information, and the burdens of patent examination. See Northern Telecom, 908 F.2d at 939, 15 USPQ2d at 1327 (discussing the ease with which routine patent prosecution may be portrayed as tainted conduct).

Following are the actions that M3 Systems presented as probative of fraud in the prosecution of the '056 or the '308 patent:

1. The Inventorship Issue

This issue was discussed ante in connection with the validity of the '056 patent. There was no evidence of intent to deceive in correcting the inventorship to include Mr. Åkerfeldt with Dr. Lindgren as joint inventors. The question of Mr. Taylor's role as a possible inventor did not present substantial evidence of fraud. Indeed, since the inventorship issue was not grounds of invalidity, it can not satisfy the "but for" test of fraud.

2. Provision of Actual Models to the Examiner

M3 Systems argued that Bard should have provided the reissue examiner with actual models of the first generation gun and the Tru-Cut needles, in addition to the PCT application and publications describing the needles. The PCT application described the first generation gun, and descriptions of the Tru-Cut needles were before the examiner. Reviewing the prosecution history we do not discern substantial evidence of material withholding, for

cumulative information is not material to patentability, and there was no evidence of deceptive intent or that the examiner was deceived into granting the reissue. This issue can not support the verdict of fraud.

3. Provision of On-Sale Information to the Examiner

Bard filed with the PTO descriptions of the transactions involving Radiplast and Pharmaseal before the critical date, accompanied by documents including the invoice for the 10 guns and 250 needles for the clinical trials, the bulk price quotation discussed ante in connection with the on-sale issue, and declarations concerning the hospital tests and the proposed distribution relationship between Radiplast and Pharmaseal. M3 Systems states that Bard should have also disclosed to the PTO Radiplast's sales activities for the first generation device Radiplast's letters to doctors concerning the clinical trials, the fact that the bulk price quotation included a profit, and Radiplast's letter to Dr. Phelps.

Concerning Dr. Phelps, Bard answers that it submitted to the PTO all the relevant material it had obtained. The letter to Dr. Phelps was obtained after suit was filed, during discovery of Radiplast's files in Sweden. There was no evidence that Bard had obtained and withheld this information during the reissue prosecution. With respect to the bulk price quotation, M3 Systems states that Bard should have flagged this document and described its significance to the examiner, lest it be overlooked in the volume of paper. Bard responds that the documents provided to the examiner were a record of Radiplast's efforts to find a distributor and its transactions with Pharmaseal, and that the total number of documents was not so voluminous, or the contents so difficult to understand, as to support an inference of intentional

concealment of any particular document that was filed. We agree that these documents, all in the prosecution history, are easily read.[6]

On reviewing these filings in the PTO we have been directed to no evidence of material withholding or the provision of false information, or of intent to deceive or actual deception. The additional subject matter that M. states should have been included was not shown to be material or other than cumulative. These actions did not constitute substantial evidence of fraud.

4. Disclosure of the Information Filed with the FDA

None of the material provided us with respect to Radiplast's 510(k) pre-market notification filed with the Food & Drug Administration supports a finding of fraud in the patent prosecution. M3 Systems concentrates on the presence in this package of needle drawings made by Hart Enterprises, the designated manufacturer. As we have explained, the inventorship issues that have been raised do not provide substantial evidence of fraudulent procurement of these patents.

5. Disclosure of the PCT Application

The PCT application had been submitted to the PTO during prosecution of the '154 patent and again during the '056 reissue proceedings. M3 Systems states that Bard

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[6] The record provided us does not show any response from the PTO. Although Bard states that "the [PTO] determined that the transfers to American Pharmaseal [] were for primarily experimental purposes and therefore did not trigger the bar," the record citations do not relate to this statement.

withheld the PCT application from the examiner of the '308 patent and then mischaracterized it.

M3 Systems stated at trial and repeats on this appeal that Bard submitted the PCT application to the examiner of the '308 patent only after allowance of the '308 claims in suit, and then falsely represented that it was relevant solely to newly added claims 21-23 (as then numbered). Bard complains that M3 misstated at trial, and continues to misstate, these facts. We must agree. The '308 prosecution history in the record shows that Bard cited the PCT application and filed a copy thereof with a Supplemental Information Disclosure Statement accompanying Bard's first response, filed October 13, 1989, to the first Office Action. Contrary to M3's statements, the prosecution record shows that no claims had been allowed or held allowable when the PCT application was submitted to the PTO.

In submitting the PCT Application Bard's patent attorney pointed out the aspect of that application that M3 Systems has stated is of greatest significance, viz., the separate and thus sequential hand cocking of the springs in the first generation device. In the Remarks section of the response Bard discussed claims 21-23, the claims specific to sequential energizing. We discern no support for M3's argument that Bard misrepresented the content of the PCT application, or that the examiner did not consider the PCT application adequately. The examiner initialed on December 15, 1989 that he had considered this reference, the same day a telephone interview was held that led to an examiner's amendment, followed by allowance on January 3, 1990. The charge of fraud based on these events is totally without substance.

Conclusion

These asserted flaws in patent prosecution, separately or taken together, do not constitute substantial evidence of fraud. The verdicts of fraud in procuring the '056 and '308 patents can not stand, and the judgment on these verdicts is reversed.

VI

ANTITRUST ISSUES

Antitrust violation was found on special verdicts that Bard by anticompetitive conduct had monopolized or attempted to monopolize the relevant markets for each of fully automated biopsy guns and needles, guns alone, and replacement needles. The jury instructions on the antitrust count identified three separate claims; first, that the patents were procured by fraud followed by attempts to enforce the fraudulently procured patents; second, that Bard threatened and then brought suit knowing that its patents were invalid, unenforceable, or not infringed; and third, that Bard unlawfully leveraged its monopoly power in the guns to obtain a competitive advantage in replacement needles by modifying its gun to accept only Bard needles. The jury found in favor of M3 Systems and against Bard on every question, and assessed compensatory damages, measured primarily as litigation costs, of $1.5 million, which were trebled as required by section 4 of the Clayton Act. Bard argues that the findings are not supported by substantial evidence, and that judgment as a matter of law should have been granted.

A. The Walker Process Claim

Fraud in obtaining a United States patent is a classical ground of invalidity or unenforceability of the patent. In Walker Process, 382 U.S. 172, 147 USPQ 404 the Court established that antitrust liability under section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition. Restraint on competition based on power in the relevant market must be established on the criteria of section 2, when the patent has been fraudulently obtained. See Nobelpharma, 141 F.3d at 1068, 46 USPQ2d at 1104;[7] Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455-56 (1993) (explaining Walker Process as requiring appraisal of the exclusionary power of the fraudulently obtained patent in terms of the relevant market for the product involved).

The jury found by special verdicts that the '056 and '308 patents were obtained by fraud in their prosecution before the PTO, as discussed in Part V, ante. The jury also found that "there is a relevant product market" for the biopsy guns and needles, together and separately, that Bard had monopoly power in each market and had "engaged in restrictive or exclusionary conduct with the conscious object of acquiring monopoly power in the market."

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[7] In Nobelpharma the Federal Circuit held in banc that Federal Circuit law would thenceforth apply to determination of whether fraudulent conduct occurred in obtaining a patent, whereas determination of the other elements of the section 2 violation, viz. market power in the relevant market and illegal restraints on competition, since not unique to the patent right would continue to be governed by regional circuit law. 141 F.3d at 1067-68, 46 USPQ2d at 1104.

It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms. See Abbott Labs. v. Brennan, 952 F.2d 1346, 1354, 21 USPQ2d 1192, 1199 (Fed. Cir. 1991) (possession of patent, and market advantages thus gained, do not establish antitrust market power). The virtually unlimited variety and scope of patented inventions and market situations militate against *per se* rules in these complex areas. Unless the patent had been obtained by fraud such that the market position had been gained illegally, the patent right to exclude does not constitute monopoly power prohibited by the Sherman Act. Walker Process, 382 U.S. at 177-78, 147 USPQ at 407. As the Second Circuit stated in SCM Corp. v. Xerox Corp., "No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market." 645 F.2d 1195, 1204, 209 USPQ 889, 899 (2d Cir. 1981).

Thus it was necessary for M3 Systems to establish market power as well as fraudulent procurement of the patent and that Bard's related commercial activity was coupled with violations of section 2. In addition, applying the law of the Seventh Circuit to the elements of section 2, M3 was required to establish that Bard had a specific intent to monopolize, engaged in anti-competitive conduct, and had a dangerous probability of success. See Great Escape, Inc. v. Union City Body Co., 791 F.2d 532, 540 (7th Cir. 1986). These issues were argued at trial, and by special verdicts the jury found culpability on the part of Bard. However, in view of the incorrect verdicts on the question of fraud in procurement of the '056 and '308 patents, as discussed in Part V, as a matter of law the judgment of

antitrust violation can not be sustained on Walker Process grounds.

B. "Sham" Litigation

Conduct prohibited under antitrust law includes bringing suit to enforce a patent with knowledge that the patent is invalid or not infringed, and the litigation is conducted for anti-competitive purposes. In such events the antitrust immunity of Noerr-Pennington and California Motor Transp. Co. v. Trucking Unltd., 404 U.S. 508 (1972) does not apply to those who seek redress through judicial process.

The Supreme Court in Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. (PRE) established the two-part criteria of "sham" litigation: (1) the lawsuit must be objectively meritless such that "no reasonable litigant could expect success on the merits" and (2) it must be found that "the baseless lawsuit conceals 'an attempt to interfere *directly* with the business relationships of a competitor.'" 508 U.S. 49, 60, 26 USPQ2d 1641, 1646 (1993) (emphasis in original) (quoting Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)). The Court declined to decide "whether and, if so, to what extent Noerr permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations." PRE, 508 U.S. at 62 & n.6, 26 USPQ2d at 1646-47 & n.6. Fraud in the procurement of a patent is governed by Walker Process and, as in PRE, the complainant "must still prove a substantive antitrust violation." PRE, 501 U.S. at 61, 26 USPQ2d at 1646.

Thus although sham litigation as a tactic to destroy competition can lead to antitrust violation, see U.S. Phillips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 597,

34 USPQ2d 1699, 1703 (Fed. Cir. 1995); cf. Handgards Inc. v. Ethicon, Inc., 743 F.2d 1282, 1288, 223 USPQ 214, 222-23 (9th Cir. 1984) (addressing Noerr-Pennington issue and explaining that to invoke "sham" exception the claimant must show "some abuse of process," and requiring clear and convincing evidence of bad faith), sham litigation requires more than a failed legal theory. PRE, 508 U.S. at 60-61 & n.5, 26 USPQ2d at 1646 & n.5; see Carroll Touch, Inc. v. Electro-Mechanical Sys., Inc., 15 F.3d 1573, 1582, 27 USPQ2d 1836, 1844 (Fed. Cir. 1993).

Neither the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability. Cf. Concrete Unltd. Inc. v. Cementcraft, Inc., 776 F.2d 1537, 1539, 227 USPQ 784, 785 (Fed. Cir. 1985) (no liability for unfair competition based on suit to enforce an invalid patent). Since a principal purpose of the patent system is to provide innovators with a property right upon which investment and other commercial commitments can be made, absent the PRE criteria the patentee must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent's validity or infringement not survive litigation. See id. The law recognizes a presumption that the assertion of a duly granted patent is made in good faith, see Virtue v. Creamery Package Mfg. Co., 227 U.S. 8, 37-38 (1913); this presumption is overcome only by affirmative evidence of bad faith. See PRE, supra.

M3 Systems states that Bard knew its patents were not infringed when it brought suit, citing the testimony of a Bard engineer that he did not think the original M3 needle infringed the '056 patent and that other Bard employees had told him that M3 changed its needle design to one that did not infringe. The engineer also testified that he did not

know whether those who told him M3's needles did not infringe had ever read the '056 patent, or whether they were familiar with the concept of infringement under the doctrine of equivalents. This was the totality of the evidence of sham litigation concerning the '056 patent; there was no evidence at all with respect to the '308 patent.[8] This does not constitute substantial evidence that this litigation was objectively meritless and brought in bad faith. The judgment of antitrust violation can not be upheld on sham litigation grounds.

C. Attempt to Monopolize[9]

M3 Systems proposed that Bard had modified its biopsy gun and needles for the purpose of preventing use of Tru-Cut needles and then to exclude M3's copies so that they did not fit the gun without an adapter. M3 contends that Bard's motives were anti-competitive, pointing to Bard documents showing internal discussions of competitive products and concern for patent scope and market share. Bard replies that the Tru-Cut was not suitable for its new gun because it could not achieve reverse motion, and points out that M3's witness acknowledged that M3 could

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[8] M3 in its brief states that: "The Jury specifically found that BARD had 'actual knowledge' that M3 did not infringe its patents or that the patents were invalid. [A10096; 11-3 ¶¶6.11]" There is no specific finding in the verdict form of "actual knowledge." The cites to ¶¶6 & 11 are to the jury's finding of patent misuse, and the jury instructions at A10096 concern the duty of candor to the PTO. The source of the quoted "actual knowledge" is not given. Such misdirections are not helpful to the appellate tribunal; see also note 6, supra.

[9] The court has affirmed the district court's judgment of antitrust violation on this ground: see the separate opinion of Judge Bryson, joined by Chief Judge Mayer. This section contains the dissenting opinion of Judge Newman.

effectively compete, as were several other producers of biopsy guns and needles.

Bard was under no duty to facilitate M3's competition by refraining from changing its products. The jury instructions did not distinguish patent-supported products and markets based thereon from actions described to the jury as being in restraint of trade. For example, the jury instruction on intent to monopolize was as follows:

> M3 Systems ~~also~~ alleges that it was injured by Bard's unlawful attempt to monopolize. An attempt to monopolize may be proven even if Bard lacks monopoly power, but because of its alleged exclusionary conduct, there exists a dangerous probability that Bard will obtain monopoly power in any market. In order to win on its claims of attempted monopolization, M3 Systems must prove each of the following elements by a preponderance of the evidence:
>
> > First, that Bard had a specific intent to achieve monopoly power in a relevant market; second, that Bard engaged in exclusionary or restrictive conduct in furtherance of its specific intent; third, that there was a dangerous probability that Bard would obtain monopoly power in the relevant market; and, fourth, that M3 Systems was injured in its business or property by Bard's conduct.

In explaining further, the district court referred to "exclusionary or restrictive conduct" and "unreasonable acts and practices," again without reference to patented products and their status in the law. Although the court instructed that "conduct that involves the introduction of

superior products" is not exclusionary or restrictive, the court also stated that "where conduct is ambiguous, direct evidence of a specific intent to monopolize may lead you to conclude that the conduct was intended to be and was in fact exclusionary or restrictive." No mention was made of the patentee's statutory right to exclude, and there was no instruction to consider that right.

These broadly stated descriptions of exclusionary or restrictive conduct, unlimited by the conditions set in Walker Process or PRE and taking no cognizance of the legal rights of the patent grant, do not rise to the level of violation of antitrust law. Thus I must, respectfully, dissent from the court's ruling that Bard incurred liability under the Sherman and Clayton Acts by its actions in modifying and improving its patented products, thereby requiring M3 to provide an adapter with its replacement needles for the Bard gun.

The panel majority on this issue holds that the jury verdict of monopoly power must be sustained, although the power held by Bard in this market is based on the patent right. Bard or its predecessor Radiplast changed from the Tru-Cut to a newly designed needle that was capable of reverse movement, thus facilitating removal, inspection, and reinsertion of the inner needle while the cannula remained in place. This needle assembly is the subject of the '056 patent. The record states that M3 was obliged to use an adapter to fit its existing needles to Bard's gun; that is the antitrust ill of which M3 complained. This does not, as a matter of law, present a jury question of violation of the Sherman Act. See California Computer Prods., Inc. v. International Bus. Mach. Corp., 613 F.2d 727, 744 (9th Cir. 1979) (when the innovation is an improvement, that it affects competition is not an antitrust violation, and no jury question arises).

Both the needle assembly alone and the integrated biopsy gun/needle device were patented. They were subject to Bard's patent-based rights to exclude others from making, using, or selling them. It was not Bard's changes to its biopsy gun or needles that affected M3's sale of replacement needles; it was the patents on these products. To hold that Bard could violate the Sherman Act by changing these products, if M3's business was adversely affected, is a novel and pernicious theory of antitrust law that is contrary to the principles of competition, and fraught with litigation-generating mischief.

Despite this court's recent affirmation in Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 873-74, 45 USPQ2d 1225, 1236 (Fed. Cir. 1997) that "a patentee may lawfully police a market that is effectively defined by its patent," this court now holds that changing and improving one's proprietary product that has created its own market niche, if to a competitor's potential disadvantage, is actionable under the Sherman Act. The competition-favoring rule is that an innovator has no duty to help its competitors: "It is the possibility of success in the marketplace, attributable to superior performance, that provides the incentives on which the proper functioning of our competitive economy rests." Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 281 (2d Cir. 1979). In California Computer the court observed that "[IBM] was under no duty to help CalComp or other peripheral equipment manufacturers survive or expand." 613 F.2d at 744. This court has today created a new, vague, and unworkable cause of action, of clear public detriment, with no balancing public benefit.

The concept that antitrust law should bar an innovator from making changes or improvements to its products, when others may be affected thereby, is not brand

new. However, cases where this issue has been litigated have been of a different order of competitive impact than here asserted; and I have found no case in which such a charge has been sustained. In In re IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1002-05 (N.D. Cal. 1979), aff'd sub nom. Transamerica Computer Co. v. International Bus. Mach. Corp., 698 F.2d 1377 (9th Cir. 1983), cited by the panel majority, the district court declined to assess liability for IBM's interface changes that prevented use of competitors' peripheral devices when "the contested changes were improvements in the products, were not unreasonably restrictive of competition, and hence did not violate the Sherman Act." Id. at 1382.

A basic premise of patent law, and antitrust law in general, is that the commercial advantage gained by new technology, and its statutory protection by patent, do not convert the possessor thereof into a prohibited monopolist. In United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966) the Court distinguished the willful acquisition or maintenance of monopoly power from "growth or development as a consequence of a superior product, business acumen, or historic accident." See also Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 1, 37 n.7 (1984) ("A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffices to demonstrate market power.") (O'Connor, J., concurring); A.I. Root Co. v. Computer Dynamics, Inc., 806 F.2d 673, 676 (6th Cir. 1986) (rejecting "any absolute presumption of market power for copyright or patented product").

When the market for new technology is protected by patent, to violate the antitrust law there must be an improper use of the patent right, "coupled with violations of §2." Walker Process, 382 U.S. at 177-78, 147 USPQ at

407. In Walker Process the Court again explained that a patent does not of itself establish a presumption of market power in the antitrust sense. Id. at 178, 147 USPQ at 406. In American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367, 220 USPQ 763, 776 (Fed. Cir. 1984), this court wrote that "patent rights are not legal monopolies in the antitrust sense of the word." Yet in the case now before us the jury was asked to determine simply whether Bard had monopoly power in a relevant market, without reference to whether the "exclusionary conduct" of which M3 complained was the conduct of the patent law.

M3 did not allege the elements of an antitrust violation when patents are involved. See, e.g., Double D Spotting Service, Inc. v. Supervalu, Inc., 136 F.3d 554, 558 (8th Cir. 1998) ("'The essential elements of a private antitrust claim must be alleged in more than vague and conclusory terms to prevent dismissal of the complaint on a defendant's [Rule] 12(b)(6) motion.'") (quoting Crane & Shovel Sales Corp. v. Bucyrus-Erie Co., 854 F.2d 802, 805 (6th Cir. 1988)); Okusami v. Psychiatric Institute of Washington, Inc., 959 F.2d 1062, 1065 (D.C. Cir. 1992) ("[T]he plaintiff's antitrust claims, lacking the essential element of an agreement, were properly dismissed for failure to state a claim upon which relief could be granted.") Dismissal for failure to state a claim was the proper response to M3's undifferentiated assertion of anticompetitive practices.

I need not elaborate on the litigation opportunity affecting innovation-based industry, that is here so casually enabled. "Where competitors' products must interface with the monopolist's product the monopolist's introduction of a new product that makes that interconnection more difficult or expensive might violate Section 2, although no court has specifically so held." 1 American Bar Assoc., Antitrust

Law Developments 286 (4th ed. 1997) (emphasis added). As a sister circuit recently stated, "Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law." United States v. Microsoft Corp., 147 F.3d 935, 948 (D.C. Cir. 1998).

The proceedings at trial, and the jury instructions, made no mention of the patent rights here present. It is without precedent to find antitrust liability premised on a theory that development of new products is illegally anticompetitive when the new product requires competing suppliers to adjust their product accordingly. Commentators who have considered the question of "whether product innovation can ever be unlawfully 'predatory'" have concluded that "no administrable rule could be fashioned that would not exact an unreasonably heavy toll." 3 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law §705b (rev. ed. 1996). If this court deems it appropriate to add this burden to patent-based innovation, there should at least be some overriding public benefit. However, antitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation. See IBM Peripherals, supra.

Neither the jury instructions nor the special interrogatories framed a charge of predatory conduct that comports with established criteria of antitrust liability. It appears that this charge at trial was cobbled together from left-over allegations of bad acts by bad actors. Indeed, M3's antitrust counterclaims mention only Walker Process fraud and sham litigation, which all members of this panel agree were not established. I can not discern, in the law or in the record of this case, either legal or factual support for this new form of antitrust liability.

VII

MISUSE; OTHER ISSUES

The defense of patent misuse arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage. Patent misuse relates primarily to a patentee's actions that affect competition in unpatented goods or that otherwise extend the economic effect beyond the scope of the patent grant. See Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 703-04, 24 USPQ2d 1173, 1176 (Fed. Cir. 1992) ("The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that draw anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.")

Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude. Thus misuse may arise when the conditions of antitrust violation are not met. See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 140-41, 161 USPQ 577, 597 (1969). The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect. See Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 868, 45 USPQ2d 1225, 1231-32 (Fed. Cir. 1997); B. Braun Medical, Inc. v. Abbott Labs., 124 F.3d 1419, 1426, 43 USPQ2d 1896, 1902 (Fed. Cir. 1997); Mallinckrodt, 976 F.2d at 704, 24 USPQ2d at 1176.

The jury returned special verdicts that Bard had misused both the '056 and '308 patents. Patent misuse arises in equity, and a holding of misuse renders the patent

unenforceable until the misue is purged; it does not, of itself, invalidate the patent. See Morton Salt Co. v. G. S. Suppinger, Co., 314 U.S. 488 (1942); Senza-Gel Corp. v. Seiffhart, 803 F.2d 661, 668 n.10, 231 USPQ 363, 368 n.10 (Fed. Cir. 1986). When a jury has determined that patent misuse occurred we review the underlying findings of fact for support by substantial evidence, presuming that the jury resolved any factual disputes in favor of the verdict winner. We then determine whether, on the found or presumed facts, the conclusion on the issue of misuse is correct. See Virginia Panel, 133 F.3d at 866, 45 USPQ2d at 1231-32.

The jury instruction on patent misuse was focussed primarily on the charge that Bard was attempting to enforce the patents against goods known not to be infringing, the court explaining that antitrust violation is not necessary to find misuse if patents have been used "wrongfully" to exclude competitors:

> A patent is unenforceable for misuse if the patent owner attempts to exclude products from the marketplace which do not infringe the claims of the patent and the patent owner has actual knowledge that those products do not infringe any claim of the patents. The patent is also unenforceable for misuse when a patent owner attempts to use the patent to exclude competitors from their marketplace knowing that the patent was invalid or unenforceable.
>
> A patent will not be rendered unenforceable for misuse if the patent owner has enforced the patent in the good faith belief that the accused products infringed the patent's claims.
>
> You may consider all aspects of the conduct of the patent owner in deciding whether a patent has

> been misused. In order to find misuse, you may not determine that -- you need not determine that an antitrust violation has been proved. Even if an antitrust violation has not been proven, you may still find that the patents have been misused if you conclude that the patents have been used wrongfully.

This instruction calls to mind the view expressed in USM Corp. v. SPS Techs., Inc., 694 F.2d 506, 510, 216 USPQ 959, 963 (7th Cir. 1982) that the misuse doctrine is "too vague a formulation to be useful." Although the defense of patent misuse indeed evolved to protect against "wrongful" use of patents, the catalog of practices labelled "patent misuse" does not include a general notion of "wrongful" use. See id. ("in application, the doctrine has largely been confined to a handful of specific practices").

M3 Systems did not propose any of the classic grounds of patent misuse, such as tying or enforced package licensing or price restraints or extended royalty terms, see Chisum, supra, §19.04[3], but generally urged the view that Bard's actions, even if not illegal, were an improper use of patents. Although the law should not condone wrongful commercial activity, the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce.

There was no evidence that Bard's competitive activities were either *per se* patent misuse or that they were not "reasonably within the patent grant." See Mallinckrodt, 976 F.2d at 708, 24 USPQ2d at 1180. The conduct to which the jury instruction on misuse generally refers, that is, "wrongful" enforcement of patents, is activity protected under Noerr and California Motor, and is not subject to collateral attack as a new ground of "misuse." M3 Systems

adduced no evidence of patent misuse other than was presented for its antitrust claims. It is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, nor is otherwise legal competition such behavior as to warrant creation of a new class of prohibited commercial conduct when patents are involved.

The verdicts of patent misuse are not supported by evidence or correct legal theory. The judgment on these verdicts is reversed.

Other Arguments/Issues

We have not discussed every minor argument and issue raised in this appeal. All have been considered, and we have discussed those of relevance. With respect to Bard's frequent references to jury prejudice resulting from disclosure to the jury of Bard's recent civil penalties and criminal convictions for several violations of Food and Drug Administration laws and regulations, we take note that no motion for a new trial was made on this ground, and the issue is not before us for review.

Costs

No costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1165

C.R. BARD, INC.,

Plaintiff-Appellant,

v.

M3 SYSTEMS, INC.,

Defendant-Appellee.

MAYER, Chief Judge, concurring-in-part and dissenting-in-part.

I join the court's opinion as it pertains to the validity and infringement of the '308 patent, and agree that the jury's verdict on fraud cannot stand. I join Judge Bryson's opinion sustaining the jury verdict on M3's antitrust counterclaim and remanding. My views on the validity of the '056 patent follow.

By special interrogatory, a jury found each of the disputed claims of the '056 patent invalid because the claimed invention was on sale in the United States more than one year before July 30, 1986, the filing date of the '056 patent's parent application. M3 Systems presented the jury with two reasons why the invention may be invalid for violation of the on sale bar: a transfer from Radiplast to Pharmaseal of 250 needles in June 1985 and an offer from Radiplast to Dr. Ronald Phelps in November 1984. We may affirm the invalidity verdict on either basis. See, e.g., Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582, 40 USPQ2d 1019, 1027 (Fed. Cir.

1996). Because I believe that the jury had substantial evidence that Radiplast placed the invention claimed in the '056 patent on sale in November 1984, I would sustain the jury's verdict of invalidity.

Discussion

An inventor who places his invention "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States" loses his right to patent the invention. 35 U.S.C. § 102(b) (1994). A determination that a product was placed on sale under section 102(b) is a question of law, based on underlying facts. See, e.g., KeyStone Retaining Wall Sys. Inc. v. Westrock, Inc., 997 F.2d 1444, 1451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993). While we review the trial court's ultimate determination of a section 102(b) bar de novo, see, e.g., Ferag AG v. Quipp, Inc., 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1515 (Fed. Cir. 1995); U.S. Environmental Products Inc. v. Westall, 911 F.2d 713, 715, 15 USPQ2d 1898, 1900 (Fed. Cir. 1990), in considering its denial of Bard's motion for judgment as a matter of law, we review the jury's verdict, as did the trial court, for substantial evidence. See, e.g., Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed. Cir. 1985); Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1513, 220 USPQ 929, 936 (Fed. Cir. 1984). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir. 1984).

We are guided in our review of the legal conclusion by principles underlying the on sale bar: broad and prompt

disclosure of inventions to the public; providing opportunity to experiment, improve, and determine the market value of inventions; discouraging inventors from withdrawing inventions that the public has already come to believe are freely available; and discouraging commercialization that expands the patent system's grant of the right to exclude others. See, e.g. Envirotech Corp. v. Westech Eng'g, Inc., 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990); King Instrument Corp. v. Otari Corp., 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985); General Electric Co. v. United States, 654 F.2d 55, 61, 211 USPQ 867, 873 (Ct. Cl. 1981). Because the ultimate determination of whether an on sale bar exists rests on the totality of the circumstances, that is, on consideration of the unique facts of each transaction or event, no one factor necessarily controls. See, e.g., Ferag, 45 F.3d at 1566, 33 USPQ2d at 1515. Nevertheless, we have held that "[f]oremost among these is the policy of preventing inventors from exploiting the commercial value of their inventions while deferring the beginning of the statutory term. To this end, the inventor is strictly held to the requirement that he file his patent application within one year of any attempt to commercialize the invention." Ferag, 45 F.3d at 1566, 33 USPQ2d at 1515 (internal citation omitted). The inventor is entitled to the full benefit of the patent regime; the public is entitled to full, timely disclosure of the protected invention.

We are likewise guided in our review by the principle that we must presume facts necessary to support the jury verdict. See, e.g., Perkin-Elmer, 732 F.2d at 893, 221 USPQ at 673; Railroad Dynamics, 727 F.2d at 1516, 220 USPQ at 939. Given the on sale bar verdict, we assume the jury found that Radiplast made a definite offer to sell certain subject matter and that this subject matter

"fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art." UMC Elec. Co. v. United States, 816 F.2d 647, 656, 2 USPQ2d 1465, 1472 (Fed. Cir. 1987); see also LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992). Thus, on review we must affirm the verdict of invalidity of the '056 patent if these factual findings are supported by substantial evidence, and within the context of the various policies underlying the on sale bar, the totality of circumstances supports the ultimate legal conclusion.

I. Offer for Sale

On September 25, 1984, Ronald Phelps, an Alabama medical doctor, sent Radiplast AB a letter that stated: "I am interested in learning more about the new device for percutaneous needle biopsy pictured on the enclosed brochure. I would appreciate it if you would send me all the information you have pertaining to the instrument. Also, please include a price list. Thank you." Phelps included with this letter a brochure entitled "Radi-biopsy device, a new device for percutaneous needle biopsy." This brochure described previously existing technology and then stated:

> A new device has been constructed in order to improve this biopsy method. With the aid of this instrument the biopsy procedure can be carried out with one hand, and as the movements of the obturator and cannula are automatized, better tissue specimens are obtained. All biopsies can be performed by one examiner under dynamic ultrasonic control, or under fl[uo]roscopy.

> The new device consists of a spring-trigger system for firing the two different parts of the needle -- the cannula and the obturator.
>
> It is constructed of alloyed brass and, like the pressure rod, can be autoclaved.
>
> See special instructions before using.
>
> Manufactured by . . . RADIPLAST AB . . . .

By way of its managing director, Thomas Engström, Radiplast, replied as follows to Phelps' letter on November 12, 1984:

> We thank you for your letter of [S]ept. 25[,] 1984 and for your interest in our BIOPSY DEVICE. I am truly sorry for my late reply.
>
> Our generation No. 2 of the device will we, together with our new biopsy needles suitable for the device, start marketing in USA beginning of —85, at the moment we do not know through which company.
>
> If you do not want to wait until we have our representation in USA arranged, you can allways [sic] order the device directly from us.
>
> Our price for the device is SEK 9.900,- and for the needles SEK 75,-/ea.
>
> The device is reusable and can be autoclaved. Very little service has to be done on the device due to reliable design. The needles are dispo[s]able and are designed to suit the device.
>
> I am enclosing leaflet and article.
>
> I am looking forward to hearing from you.

(Emphasis added).

The Radiplast brochure that Phelps sent to Radiplast describes a device that can be operated with one hand, by one operator, leaving the physician's other hand free to operate the ultrasound or fluoroscopy equipment. The brochure describes both parts of the needle as automatized by way of a spring-trigger system. It describes the construction materials used to manufacture the device as well as a procedure by which it can be cleaned. In short, the brochure can be understood to describe either a first generation prior art device or the second generation device described in the '056 patent.

Despite this ambiguity, Engström's reply to Phelps' letter in November 1984 is far more telling both in what it said and when it said it. His letter explicitly refers to the second generation device and "new biopsy needles suitable for the device." Since the second generation device requires a needle that moves both forward and rearward, unlike the prior art TruCut needle, Engström's letter is a clear offer for sale of the second generation device and new biopsy needles. With the exception of a reference to marketing efforts being made in the United States and the possibility of sales through a United States distributor thereafter, this letter was written entirely in the present tense.

The letter was also written after a series of correspondence between Radiplast and Hart Enterprises, a United States medical device manufacturer, addressing tooling and manufacturing costs for these new biopsy needles. On September 4, 1984, Engström had written: "Enclosed please find . . . a drawing on the biopsy needle. The stainless steel parts are not the final ones, there could be changes in length, diam. and the design of the point." On September 28, 1984, Hart Enterprises responded: "[E]nclosed are two drawings, one of the Stylet Hub and

one of the Cannula Hub for your Radiplast Biopsy Needle. If you approve these concepts we will proceed to make a prototype, and then production of the molds." Radiplast replied on October 18, 1984: "Biopsy needles: Enclosed please find our order for tooling and engineering. We approve your design of the plastic parts. The dimension from the top surface to center line of both cannula and stylet should be 4.2 mm. Regarding the needles we will probably start with 2,000 — 3,000 units bulk packed." Less than one month later, Engström sent Phelps the November 12, 1984, letter.

These facts alone are sufficient support for the jury's verdict that there was a definite offer for sale of something more than the TruCut prior art or first generation needles. However, to apply the on sale bar, the jury also had to decide whether this offer for sale of new biopsy needles was an offer of the invention claimed in the '056 patent. We review this second presumed factual finding for substantial evidence, and like the district court on its denial of Bard's motion for judgment as a matter of law, we also consider whether there may be policy considerations against imposing the on sale bar.

II. Offer of the Claimed Invention

Bard claims that Radiplast's November 1984 offer to sell second generation devices and new biopsy needles cannot trigger the bar because at that time no operable device had been made, FDA approval had not been obtained, Radiplast had not conducted clinical testing, it had not found a United States distributor, and it had not developed a final needle design. Bard misapprehends the legal significance of each of these. Clinical testing is not required before a sale can bar patent rights. Nor can subsequent clinical testing excuse a prior sale, if what was

offered for sale was the claimed invention. Clinical testing is merely one possible policy reason why a particular sale might be excused from the bar. Since Radiplast did not contemplate sales to Engström for testing purposes, the possibility of subsequent clinical testing is of no moment. Likewise, FDA approval is not required before a sale can bar patent rights. Even an illegal sale of the claimed invention before the critical date can bar patent rights. Nor is a domestic distributor relevant to the on sale bar inquiry; a sale by a foreign distributor, from a foreign country to the United States can bar patent rights. See, e.g., In re Vaceney, 761 F.2d 671, 676-77, 226 USPQ 1, 4 (Fed. Cir. 1985).

The first of Bard's two remaining arguments—that no operable device had been made—is a feint because manufacture of an operable device is not a prerequisite for application of the on sale bar. See, e.g., Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984). While operability may or may not be relevant, see, e.g., UMC, 816 F.2d at 656, 2 USPQ2d at 1472 (reduction to practice is not a requirement for application of the on sale bar), manufacture of an operable device alone is not, see, e.g., Continental Plastic Containers v. Owens Brockway Plastic Products, Inc., 141 F.3d 1073, 1078-79, 46 U.S.P.Q.2d 1277, 1281 (Fed. Cir. 1998) (declining to extend exception from public use bar under section 102(b) in design patent case). Operability is relevant only to the extent it demonstrates that a claimed element of the invention had not yet been invented, or the inventors did not know they had a workable invention and thus had nothing to offer for sale. See, e.g., Petrolite Corp. v. Baker Hughes, Inc., 96 F.3d 1423, 1427, 40 USPQ2d 1201, 1204 (Fed. Cir. 1996) ("[T]he thrust of the on-sale inquiry is whether the

inventor thought he had a product which could be and was offered to customers, not whether he could prevail under the technicalities of reduction to practice. . . ." (quoting Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 984 F.2d 1182, 1187 n.5, 25 USPQ2d 1561, 1570 n.5 (Fed. Cir. 1993)). Bard has not asserted the second circumstance, and as explained below, the alterations made after the offer for sale to Phelps did not address inventive aspects of the '056 patent's new biopsy needle.

As support for its remaining contention—that it had not developed the final design of the biopsy needle—Bard points to Engström's testimony, as managing director of Radiplast, and correspondence between Radiplast, American Pharmaseal, (one of Radiplast's potential distributors in the United States), and Alan Taylor (president of Hart Enterprises). Each of these letters was sent after the November 1984 offer for sale to Phelps, and each evidences continued testing of and proposed modifications to the second generation device and the new biopsy needles.*

Engström testified that American Pharmaseal's research and development laboratories conducted in-house testing. A technical report produced after this testing says that "testing [was] to insure functionality of the spring loaded activatior, the Biopty™ device, and the needle before releasing them to the field trial." As a result of its testing, American Pharmaseal recommended: "increas[ing]

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* Reliance on Engström's trial testimony is inherently less reliable than contemporaneous documentary evidence. Cf. TP Lab., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 972, 220 USPQ 577, 583 (Fed. Cir. 1984) (inventor's expressions of "subjective intent . . . particularly after institution of litigation, is generally of minimal value").

the strength of the stylet handle design and add[ing] the buffing operation to cannula grinding process." Engström testified that this advice was "to, how do you say, make some changes on the plastic parts and also the - - what do you call that - - well, the, for some plastic parts broke actually, so we put some, a stopper in the second generation device to prevent, if that happened, to prevent the stylet to go further on." Engström testified that on American Pharmaseal's advice, Radiplast added a "stop" to the second generation device, after the offer to Phelps.

Engström also testified that Radiplast conducted field trials in December 1985, from which it learned that "there was a potential risk for this one snapping back and hurt the doctor's hand," and "many patients thought the noise of the instrument was very disturbing." As a result, Radiplast added "an automatic retraction, a spring, actually, which took this handle back," and "some damping things, you know, to reduce the noise of the instrument." After these field trials, Engström sent a letter to Hart Enterprises on January 15, 1985, which stated: "The needle should be changed according to our phone discussion, which means that the wings of the cannula hub should have the same length. Both should be as long as the shortest wing." A letter from Hart Enterprises to Engström on January 25, 1985, enclosed three drawings that show "[t]he cannula and stylet hub dimensions are identical to the drawings and prototype you had previously received, with the exception that the cannula hub wings are now [sym]metrical."

This evidence suggests that Radiplast modified the second generation device by altering the strength of the stylet handle design, adding a buffing operation to the cannula grinding process, a stopper, automatic retraction via a spring, damping to reduce noise, and equal length symmetrical cannula hub wings as long as the shortest

wing. However, Bard cannot avoid the on sale bar merely by showing improvements to the invention after its commercialization. See, e.g., Seal-Flex, Inc. v. Athletic Track and Court Constr., 98 F.3d 1318, 1324, 40 USPQ2d 1450, 1454-55 (Fed. Cir. 1996). These changes must be something more than obvious mechanical adjustments; they have to be inventive redesigns that are claimed by the '056 patent. While some of Radiplast's changes resulted in different possible embodiments of, or additions to, the new biopsy needle that is claimed by the '056 patent, none of the changes are claimed in the text of the '056 patent. Moreover, contrary to Bard's contentions, its evidence suggests at the very least that Radiplast had "reason to expect" in November 1984, that its needle "would work for its intended purpose upon completion," Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 103 F.3d 1538, 1545, 41 USPQ2d 1238, 1244, and that Radiplast had more than a mere conception from which it was working towards development, see UMC, 816 F.2d at 657, 2 USPQ2d at 1472.

Because Bard's evidence shows nothing beyond unclaimed mechanical adjustments to the needle design claimed in the '056 patent after the November 1984 offer for sale of new biopsy needles, the jury had substantial evidence in support of its finding that the November 1984 offer for sale generated a statutory bar. See, e.g., Robotic Vision Sys., Inc. v. View Eng'g, Inc., 112 F.3d 1163, 1167, 42 USPQ2d 1619, 1623 (Fed. Cir. 1997). A contrary view would attribute to the '056 patent additional limitations taken from later developed commercial embodiments. Because the claimed invention had been completed, Engström's new biopsy needle design calls for an outcome different from Robotic Vision, 112 F.3d 1163, 42 USPQ2d 1619 (remanded for further fact finding on the completion

date of a computer software program), Micro Chemical, 103 F.3d at 1544, 41 USPQ2d at 1243 (only a proposed configuration existed and the invention remained to be completed), and Shatterproof Glass, 758 F.2d at 623, 225 USPQ at 640 (a reasonable jury could have found that "apparatus and methods of the claims were not functional".).

III. Policy Considerations

Other than the need for sufficient time to test the new biopsy needle design, which is not a policy consideration summoned by the November 1984 offer, Bard has not argued that there are policy considerations weighing against imposition of the on sale bar. Since the policies that underlie the bar focus on the inventors attempts to exploit the invention, not whether a potential purchaser was made aware of or understood it, discussion of Phelps' actual knowledge of the details of the invention or the differences between generations of the biopsy gun is irrelevant. See, e.g., Ferag, 45 F.3d at 1568, 33 USPQ2d at 1516 ("We emphasize that this is an objective test, and that at its heart lies the inventor's attempt to commercialize the invention . . . . [T]he measure of the bar is what was offered, not the patentee's intent.") In light of the strong policy of preventing exploitation of the commercial value of an invention while deferring commencement of the statutory term, I would affirm the jury's application of the on sale bar.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1165

C.R. BARD, INC.,

Plaintiff-Appellant,

v.

M3 SYSTEMS, INC.,

Defendant-Appellee.

BRYSON, Circuit Judge, concurring-in-part and dissenting-in-part.

I concur in the portion of the court's opinion upholding the jury's verdict of non-infringement of the '308 patent. I also concur in the portions of the court's opinion reversing the district court's judgment that the '308 patent is invalid, and overturning the jury's verdict on the issue of fraud. Accordingly, I join parts II-V, VI.A-B, and VII of Judge Newman's opinion.

With respect to portions of the judgment relating to the '056 patent, I agree with Chief Judge Mayer that the '056 patent is invalid under the "on-sale bar" of 35 U.S.C. § 102(b), although I take a somewhat different analytical path to that conclusion, as discussed below. Because I conclude that the '056 patent is invalid based on the on-sale bar, I do not reach the other grounds on which the jury found the '056 patent invalid.

Finally, Chief Judge Mayer and I agree that the jury verdict on M3's antitrust counterclaim must be affirmed.

Because we do not uphold all of the grounds on which the jury found liability, however, we conclude that the jury may have improperly assessed damages on liability grounds that cannot stand. We therefore must remand for further proceedings to determine the proper amount of damages to be assessed on the antitrust counterclaim.

I

With respect to the on-sale bar, I believe that the June 1985 sale of 250 needles from Radiplast to Pharmaseal was sufficient to support the jury's verdict that the asserted claims of the '056 patent were rendered invalid by a sale more than one year before July 30, 1986, the effective filing date of the patent. It is undisputed that the needles sold in June 1985 embodied the invention of the '056 patent. Whether that sale was sufficient to invoke the on-sale bar turns on whether the sale falls within the "experimental purpose" exception to the on-sale bar.

A

In the summer of 1984, Radiplast began looking for a company "to distribute and promote the sales of [its] biopsy instruments in the United States." Pharmaseal, a potential distributor of the instruments, sent a telex to Radiplast stating that "before any formal purchasing plans can be made," it would have to conduct field trials "to determine the performance and specimen quality of your biopsy device and disposable needle." Pharmaseal sent letters to several hospitals in December 1984 inviting them to participate in a "field trial as a potential sales/distribution system for Radiplast devices."

Radiplast responded by telex on January 21, 1985, setting a price for the needles to be used in Pharmaseal's

field trial and offering large-quantity discounts for batches of up to 50,000 needles. Radiplast's telex stated that "in order to be able to deliver both needles and instruments in beginning of March [1985], we need a [telex] order, preferably this week." It also stated that "we have to meet and discuss more in detail all things related with the marketing of our biopsy instrument in U.S." With respect to Pharmaseal's proposed field trial, Radiplast merely suggested that "if you would like [Dr. Lindgren, the inventor] to visit the hospitals performing the trial, in order to help them get started, he will be happy to help you."

Pharmaseal agreed to purchase the instruments and, on March 28, 1985, placed an order for 10 biopsy guns and 250 needles from Radiplast. The instruments were shipped in June 1985. It is undisputed that the June 1985 transaction constituted a sale and that the needles sold at that time embodied the invention of the '056 patent.

Pharmaseal conducted in-house testing of the devices in July 1985 before releasing the products to hospitals for the field trials. Following the in-house testing, Pharmaseal reported only minor problems and made minor manufacturing suggestions, such as recommending that Radiplast strengthen the stylet hub design and add a buffing operation to the cannula grinding process.

Although Bard contends that Dr. Lindgren attended some of the field trials and that Radiplast "was continually advised by Pharmaseal of [their] progress," Dr. Lindgren testified that he did not exercise any control over the tests, that he did not recall ever seeing the instrument used during a test, and that he did not receive or maintain any data from the tests. Bard appears to concede that the test results were not maintained in confidence, and it points to no evidence showing that the primary purpose of the tests was to ensure

that the claimed features of the invention would operate as intended.

The field testing was performed at the behest of Pharmaseal, the purchaser, not Radiplast or the inventor. Pharmaseal "assumed primary responsibility" for the tests, while Radiplast merely "had an ongoing interest" in the progress of the trials and "was kept informed" of the progress of the field trials. During the field trials, Pharmaseal and Radiplast continued to discuss market potential, potential prices and volumes, and an instructional videotape to teach proper use of the instruments.

B

Bard argues that the jury verdict cannot stand because the in-house testing at Pharmaseal and the hospital field trials show that the sale was for experimental testing purposes. The so-called "experimental testing" exception to the on-sale bar applies only if commercial exploitation is "merely incidental to the primary purpose of experimentation to perfect the invention." Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd., 731 F.2d 831, 839, 221 USPQ 561, 567 (Fed. Cir. 1984). In determining whether the inventor made the sale in question for purposes of determining whether the invention would work for its intended purpose, a court must consider various factors, such as the amount of control the inventor exercised over the testing; the length of the test period; whether any payment was made; whether there was a secrecy obligation; whether progress records were kept; whether someone other than the inventor conducted the experiments; and the degree of commercial exploitation during the tests in relation to the purpose of the experimentation. Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1564, 4 USPQ2d 1210, 1214 (Fed. Cir. 1987). Certain factors,

such as the requirement that the inventor control the testing, that detailed progress records be kept, and that the purported testers know that testing is occurring, are critical to proving experimental purpose. Lough v. Brunswick Corp., 86 F.3d 1113, 1120, 39 USPQ2d 1100, 1105 (Fed. Cir. 1996) ("if the inventor has no control over the alleged experiments, he is not experimenting"); see generally 2 Donald S. Chisum, Patents § 6.02[7][c] (1998).

The evidence shows that Radiplast's primary purpose in making the sale to Pharmaseal was to market the patented invention through Pharmaseal, not to conduct tests to determine whether the claimed invention would work for its intended purpose. Neither the in-house testing at Pharmaseal nor the field trials at hospitals were conducted under the control or supervision of the inventor or Radiplast; instead, the tests were proposed, controlled, and monitored by Pharmaseal, the purchaser. Dr. Lindgren, the inventor, admitted at trial that he had no control over the field trials, that he did not maintain any test data, and that he did not recall receiving any test results. Radiplast was not aware of the identity of the patients in the field tests, the organs that were being biopsied, or the types of tests being performed; indeed, the patients were apparently not even informed that the biopsies were being conducted as part of a test. The hospitals participating in the field trials were told that the trials were intended as "a potential sales/distribution system for Radiplast devices." There is no evidence that any secrecy agreements were made with Pharmaseal, the hospitals, or any of the test participants. Finally, it is undisputed that Pharmaseal paid for the instruments and needles used in the tests. All of these factors point away from the conclusion that the sale was made for purposes of experimentation. See Western Marine Elecs., Inc. v. Furuno Elec. Co., 764 F.2d 840, 846,

226 USPQ 334, 339 (Fed. Cir. 1985) (no experimental use where evidence pointed to market testing rather than experimentation).

Significantly, at the time of the sale of 250 needles in June 1985, Radiplast had an open offer to sell large quantities of needles to Pharmaseal at bulk discount prices. The January 21, 1985, telex had offered batches of up to 50,000 needles for a specific price, and smaller quantities of 10,000 and 20,000 needles for somewhat higher prices. The offer of such large quantities of needles was clearly for commercial, rather than experimental, purposes, and by June 1985 it was clear that the needles that were being offered to Pharmaseal embodied the later-claimed invention. The bulk purchase offer provides further evidence that the June 1985 sale was not for experimental purposes. See Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1325, 40 USPQ2d 1450, 1455 (Fed. Cir. 1996) (Bryson, J., concurring) ("if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes and that occurs more than one year before the application renders the invention unpatentable"). Thus, it appears that Radiplast was marketing the later-claimed needles commercially at least by late June 1985. Its willingness to sell smaller quantities of needles to Pharmaseal to use in its field tests was evidently an accommodation to Pharmaseal, which conducted its own tests before distributing the needles to hospitals and doctors. The fact that Radiplast recognized that Pharmaseal intended to test the needles before distributing them in bulk, however, did not make Radiplast's offer and sale in 1985 any less commercial in nature.

The facts of this case are analogous to those in U.S. Environmental Products, Inc. v. Westall, 911 F.2d 713,

15 USPQ2d 1898 (Fed. Cir. 1990). In Westall, this court affirmed a district court's conclusion that a patent was invalidated by a sale more than one year before the filing date. That conclusion was based primarily on (1) the lack of written progress records and the failure to adhere to a testing schedule; (2) the inventor's failure to maintain control over the testing; and (3) promotion of the invention during the testing. Id. at 717-18. In this case, as in Westall, the evidence shows that neither the in-house tests at Pharmaseal nor the field tests at hospitals were under the control of the inventor or his company. There is little or no evidence of any written progress records; indeed, the inventor was apparently never provided with any test results. Finally, the communications between Radiplast and Pharmaseal throughout the purported testing period emphasized commercial sales and projections, not controlled experimentation.

Bard relies heavily on Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991), for the proposition that providing price estimates for future sales does not otherwise vitiate the experimental testing exception. In Continental, however, this court noted that "no sales were ever made"; there was a joint development project between two companies to develop the invention; and the project was "cloaked in confidentiality." 948 F.2d at 1269-70, 20 USPQ2d at 1750. Because the circumstances in Continental are so different from the circumstances in this case, Continental is of no help to Bard.

C

Bard also contends that the Pharmaseal sale cannot constitute a bar under 35 U.S.C. § 102(b) because Radiplast did not make a profit on the transaction. The jury heard

testimony, however, suggesting that Radiplast made a 60% profit on the Pharmaseal sale. Even ignoring any actual profit on the devices used in the field trials, it is clear that the Pharmaseal transaction was made primarily to develop a market for future sales, not primarily to test the claimed invention. At any rate, the failure to turn a profit is not determinative. "A patent owner may have created an on-sale bar despite losing money on a sale." U.S. Envtl. Prods., Inc. v. Westall, 911 F.2d 713, 717, 15 USPQ2d 1898, 1902 (Fed. Cir. 1990).

II

In support of its antitrust counterclaim, M3 presented three theories to the jury: (1) that Bard committed fraud in the procuring its patents (the Walker Process theory); (2) that Bard acted in bad faith in enforcing its patents (the "sham litigation" theory), and (3) that Bard modified its Biopty gun for the purpose of preventing its competitors' needles from being used in that gun. Bard challenges the sufficiency of the evidence to support the jury's verdict on each of those three theories. The panel is unanimous in concluding that the evidence is insufficient to support liability on the Walker Process and "sham litigation" theories. Chief Judge Mayer and I agree, however, that there is sufficient evidence to affirm the jury's antitrust liability verdict based on Bard's gun modification program, for the reasons set forth below.

A

The jury considered evidence that Bard modified its Biopty gun to prevent its competitors' non-infringing, flangeless needles from being used in Bard's guns. By special verdicts, the jury found that there was a relevant product market for replacement needles for fully automated

reusable biopsy guns, that Bard had monopoly power in that market, and that it had acquired or maintained its monopoly power in that market through restrictive or exclusionary conduct.

In order to prevail on its claim of an antitrust violation based on Bard's modification of its Biopty gun to prevent the use of competing replacement needles, M3 was required to prove that Bard made a change in its Biopty gun for predatory reasons, i.e., for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of the gun. See In re IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1002 (N.D. Cal. 1979), aff'd sub. nom. Transamerica Computer Co. v. International Bus. Mach. Corp., 698 F.2d 1377 (9th Cir. 1983); see generally 1 ABA, Antitrust Law Developments 286-87 (4th ed. 1997). Bard argues that the evidence showed that absent patent protection for Bard's devices, M3 could still compete in the relevant market. While the evidence of Bard's market power was in dispute, the jury specifically found that Bard enjoyed monopoly power in the market for replacement needles. The evidence was sufficient to support the jury's verdict on that point and also to support the jury's conclusion that Bard maintained its monopoly position by exclusionary conduct, to wit, modifying its patented gun in order to exclude competing replacement needles.

The dissent on this issue starts from the premise that the modification to Bard's Biopty gun was an "improvement" and argues from that premise that to hold Bard liable for the modification would have the "pernicious" effect of penalizing innovators for making improvements to their products. The dissent's premise, however, is contrary to the jury's verdict, which was supported by the evidence. Although Bard contended at

trial that it modified its Biopty gun to make it easier to load and unload, there was substantial evidence that Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of "copycat" needles. One internal Bard document showed that the gun modifications had no effect on gun or needle performance; another internal document showed that the use of non-Bard needles in the gun "could not possibly result in injury to either the patient or the physician." In view of that evidence, the jury could reasonably conclude that Bard's modifications to its guns constituted "restrictive or exclusionary conduct" in a market over which it had monopoly power.

The dissent also takes issue with the jury instructions, contending that they failed properly to frame a charge of predatory conduct that comports with established criteria of antitrust liability. Because Bard did not challenge the court's instructions, however, the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal. To be entitled to relief based on asserted errors in the court's instructions to the jury, Bard was required to challenge those instructions in this court and demonstrate that it timely objected to those instructions in the district court. Bard did neither, but instead based its argument entirely on the sufficiency of the evidence. Because the evidence is sufficient to support the verdict on the gun modification theory of liability, the jury's liability verdict must stand. See Mangren Research & Dev. v. National Chem. Co., 87 F.3d 937, 942 n.3 (7th Cir. 1996); Composite Marine Propellers, Inc. v. Van Der Woude, 962 F.2d 1263, 1265 (7th Cir. 1992).

B

While we affirm Bard's liability on the antitrust counterclaim, that does not necessarily mean that the jury's damage award of $1.5 million can be sustained. M3 presented evidence of three different markets (guns, guns and needles, and replacement needles) in which Bard allegedly caused antitrust injury, and the jury found Bard liable for injury in each market. The damages portion of the verdict, however, merely indicated a general award of $1.5 million without attribution to a particular market or exclusionary practice.

M3's evidence concerning Bard's gun modification program was relevant only to the replacement needle market. Because we have concluded that the evidence concerning Bard's activities in the other two markets cannot support antitrust liability, the question arises as to whether the $1.5 million damages award can be supported solely on the basis of the injury Bard's actions caused to M3 in the replacement needle market. That issue was not briefed on appeal, and the record, so far as we can ascertain, does not provide clear guidance as to the proper allocation of damages due to the injury suffered by M3 in the injury replacement needle market. Consequently, we vacate the antitrust damages award and remand to the district court to consider, after additional hearing or limited retrial, if necessary, the proper amount of damages attributable to Bard's gun modification program. See MCI Communications Corp. v. American Tel. & Tel. Co., 708 F.2d 1081, 1166-67 (7th Cir. 1983).

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1165

C.R. BARD, INC.,

Plaintiff-Appellant,

v.

M3 SYSTEMS, INC.,

Defendant-Appellee.

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by C.R. Bard, Inc., and a response thereto having been invited by the court and filed by M3 Systems, Inc., and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges authorized to request a poll whether to rehear the appeal in banc, and a poll having been requested, taken, and failed,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

Circuit Judge Gajarsa, with whom Circuit Judge Clevenger joins, concurs in a separate opinion.

The mandate of the court will issue on December 14, 1998.

For the court,

s/ Jan Horbaly
Jan Horbaly, Clerk

December 7, 1998

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT
DEC 7 1998

JAN HORBALY
CLERK

APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

96-1165

C.R. BARD, INC.,

Plaintiff-Appellant,

v.

M3 SYSTEMS, INC.,

Defendant-Appellee.

ON SUGGESTION FOR REHEARING IN BANC

GAJARSA, Circuit Judge, concurring in the Order declining the suggestion for rehearing in banc, in which Circuit Judge Clevenger joins.

If fundamental issues at the intersection of patent law and antitrust law were being decided, I would dissent from the court's decision to deny an in banc rehearing. However, those issues are not before us. In this case, the patentee is accused of improperly redesigning a patented product, albeit within the proper scope of the claims, in order to prevent its competition from entering the market for the now

unpatented product[1] used in association with the patented device. The patentee, Bard, was charged with redesigning its patented "Biopty" gun to prevent its competitors' needles from being used in that device. The majority opinion on the antitrust issue ultimately determined that substantial evidence supported the jury's verdict that this behavior was "predatory" in violation of antitrust laws. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1383 (Fed. Cir. 1998).

Given these facts, the patent bar may, at first glance, be alarmed that the majority opinion opens the floodgates with respect to a new antitrust cause of action. However, it is important for the bar to note that the only argument Bard made on appeal regarding the antitrust violation was directed to the sufficiency of the evidence on this issue. Bard did not argue to this court that modification of a patented product within the scope of the claims by a patentee cannot, as a matter of law, constitute an antitrust violation. Nor did Bard challenge the jury instructions. See C.R. Bard, 157 F.3d at 1382 ("Because Bard did not challenge the court's instructions . . . the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal.") In light of our limited review of jury findings, the majority affirmed the jury verdict based on its determination that there was substantial evidence to support the verdict. See id. at 1383.

Consequently, this case does not establish or endorse a new antitrust theory. The majority opinion turns solely on Bard's argument regarding the sufficiency of the evidence and its failure to challenge the propriety of the jury instructions. The question of whether or not a cause of

---

[1] The patent covering the needles was held invalid by the panel majority on the basis of 35 U.S.C. § 102(b).

action premised upon the antitrust laws exists when a patentee redesigns a patented product within the scope of the patent claims, awaits another day.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1165

C.R. BARD, INC,

Plaintiff-Appellant,

v.

M3 SYSTEM, INC.,

Defendant-Appellee.

JUDGMENT

ON APPEAL from the	United States District Court for the Northern District of Illinois
In CASE NO(S).	93-CV-4788

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:	AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED.

ENTERED BY
ORDER OF THE COURT

DATED Sep 30, 1998 s/ Jan Horbaly
Jan Horbaly, Clerk

ISSUED AS A MANDATE: DECEMBER 14, 1998

APPENDIX E

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

Eastern Division

JUDGMENT IN A CIVIL CASE

C.R. Bard, Inc.,

Vs.

CASE NUMBER: 93 C 4788

M3 Systems, Inc.,

[X] Jury Verdict. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

[ ] Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that judgment is entered in favor of defendant, M3 Systems, Inc. and against plaintiff, C.R. Bard, Inc. in the amount of $4,500,000.00 (trebling the jury verdict of $1,500,000.00 as required).

December 18, 1995
Date

H. Stuart Cunningham
Clerk

s/
(By) Deputy Clerk

(2)

Supreme Court, U.S.
FILED
MAR 29 1999
OFFICE OF THE CLERK

No. 98-1373

In The

Supreme Court of the United States

October Term, 1998

C.R. BARD, INC.,

Petitioner,

v.

M3 SYSTEMS, INC.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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2918

PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of the *Petition for Writ of Certiorari.*

Respondent is M3 Systems, Inc. ("M3"). Pursuant to Supreme Court Rule 29.6 respondent states that it is wholly owned by Manan Medical Products, Inc., which is wholly owned by The Marmon Corporation, which is wholly owned by Marmon Holdings, Inc.

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STATEMENT OF THE CASE

A. The Antitrust Question

1. Statement Of Facts Pertaining To The Antitrust Question

Petitioner, C.R. Bard, Inc. ("Bard"), manufactures automatic biopsy guns. The jury, pursuant to agreed instructions, found that (1) such guns constitute a relevant economic market, and (2) Bard possessed monopoly power in that market. (A 28).[1]

Bard also manufactures biopsy needles which are placed in the automatic gun and shot into a patient to extract tissue for study. The jury found that such needles constitute a second relevant economic market and that Bard obtained monopoly power over that market by the exclusionary conduct described below (A 29).

Respondent, M3 Systems, Inc. ("M3"), manufactured competing biopsy needles usable in Bard's monopoly gun. (2a). In order to avoid Bard's claim that they were infringing Bard's '056 patent, M3 and other competitors redesigned the hubs of their biopsy needles by removing two flanges. (A 15099-116, A 8876-77, A 14504-21, A 7300, A 14968). These flangeless needles worked perfectly well with Bard's gun (A 7295-6, A 8768-73) but did not infringe the '056 patent. (A 13-14, 2a-3a, 79a).

After M3 and other competitors removed the flanges from their needle hubs, Bard modified its automatic gun

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[1] The Joint Appellate Appendix is cited as A ___; Petitioner's Appendix in this Court is cited ___a; and the trial court record is cited as R. ___.

by removing the rear push plate or sled. (A 8327-32, A 8768-73, A 8871-2, A 14517). This prevented the non-infringing, flangeless needles from working in Bard's gun. (A 7174-80, A 8330-2, A 8768-9, A 8876, A 14504, A 15105). Indeed, Bard made this modification explicitly to prevent the use of competitors' non-infringing, flangeless needles with its monopoly gun. (A 8327-32, A 7107-8, A 8768-73, A 8871-72, A 8881-3, A 14517, 86a-87a, Pet. 6). As a Bard memo admits, "the intent of performing this modification is to assure that only needles manufactured according to the Bard patented design can be used with the [Bard gun]." (A 14504).

The removal of the rear push plate from Bard's gun did not improve the gun's performance. The jury was instructed that conduct could "never" be deemed exclusionary if it "involves the introduction of superior products" (A 10120) or "offering better products or services" (A 10113). The jury, however, found Bard's modification of its gun to be exclusionary. (A 29). The appellate court confirmed that "Bard's real reasons for modifying the gun" were to exclude non-infringing, competitive needles from the market and not to make any "improvement" in the gun. (87a-88a). Indeed, the evidence showed that the modification made the gun harder to use and caused doctors to complain. (A 8871-91). Bard's own documents admit that the modification did not improve the gun's performance. (88a, A 14504-5).

Bard not only removed the rear push plate from new guns, but also secretly and without customer permission removed the rear push plate from customer owned guns which were sent to Bard for repair or refurbishment. As a result, the gun owners could no longer use competitors'

non-infringing, flangeless needles after the guns were returned. (A 6859-60, A 8875-6). Customers complained about this conduct and several Bard executives proposed that the gun owners be given the choice of receiving back their unmodified guns. (A 8873-4). This proposal was rejected because Bard "wanted to continue to try to gain market share with our needles." (A 8874). Bard, with a 75% market share in needles, admitted that its intent was to aggressively remove from the field any gun which was compatible with a competitor's flangeless needle so as to "make it difficult for Manan to compete" and to obtain "biopsy dominance." (A 8882-3, A 15107).

Bard also placed a prominent warning label on all modified guns. This label stated: "Caution. Use only Bard Biopty-cut biopsy needles with this instrument." (A 8360). This was done even though there were no instances of a non-Bard needle injuring a patient due to its use with the Bard gun. (A 7174-80, A 7185-6). Bard admitted at trial that due to malpractice concerns no doctor would use a competing needle with Bard's gun after the warning label appeared. (A 8359).

2. The Antitrust Ruling In The District Court

The jury was instructed that M3's monopoly leveraging theory was that Bard, by modifying its gun so as to preclude use of competing needles, had used monopoly power over the gun market to obtain monopoly power over the needle market. (A 10104, A 10115-8). This theory was plainly set forth in the pre-trial order, which, pursuant to Federal Rule of Civil Procedure 16(e), "shall

control the subsequent course of the action." (A 534 R. 57, p. 14).

The monopoly leveraging instructions were agreed and not objected to by Bard. (88a). The jury was told that mere possession of monopoly power is not unlawful (A 10114); that a violation results only if monopoly power is obtained by "exclusionary acts" and that making improved or better products "can never be found to be exclusionary." (A 10120-1). The jury nevertheless found Bard's conduct exclusionary and returned a verdict for M3 on the monopoly leveraging claim. (A 29).

At the close of M3's case, Bard moved for judgment as a matter of law ("JMOL") on several of M3's antitrust theories. Bard's motion, however, did not utter a single word about the gun modification/monopoly leveraging theory. (A 5270-357, R. 302). After the jury returned its verdict, Bard renewed its motion for JMOL. (A 5270). Despite the fact that arguments not made in the pre-verdict motion for JMOL are deemed waived,[2] Bard argued that the gun modification verdict was defective, but only due to an asserted insufficiency of the evidence to meet the elements in the agreed instructions. (A 5354-6 R. 302, pp. 79-81). Bard's motion was denied. (A 2-3).

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[2] *See* F.R.C.P. 50; *Kutner Buick, Inc. v. American Motor Corp.*, 848 F.2d 614, 617 (3rd Cir. 1989); *Kinzenbrew v. Deere & Co.*, 741 F.2d 383, 387 (Fed. Cir. 1984).

3. The Antitrust Ruling In The Federal Circuit

In its main brief to the Federal Circuit, Bard devoted only two pages to M3's three antitrust theories. As in the trial court, Bard did not challenge the viability of M3's legal theories. Rather, Bard's only attack on the antitrust judgment was that "there was no substantial evidence supporting any of [M3's antitrust] theories." (Bard App. Br. 48-49).

With regard to the monopoly leveraging theory on which *certiorari* is now sought, Bard's argument consisted of exactly two sentences. In conclusory fashion, Bard argued that the gun modification could not be unlawful because under Bard's rejected view of the evidence, M3 could still compete. (Bard App. Br. 49-50).

The Federal Circuit opinion, authored by Judge Bryson and joined by Chief Judge Mayer, affirmed that Bard had used its monopoly power over biopsy guns to obtain monopoly power over biopsy needles. (86a-89a). The Court pointed out that on appeal Bard did not challenge the adequacy of M3's legal theory, but merely "the sufficiency of the evidence to support the jury's verdict." (86a). The Court then held that the jury had been presented with "evidence that Bard modified its Biopty gun to prevent its competitors' non-infringing, flangeless needles from being used in Bard's guns." (86a). The majority also approved the jury's findings that biopsy needles constituted a relevant market; that Bard had obtained monopoly power in that market; and that it had done so through exclusionary conduct. (86a-87a).

The majority noted that in order to prevail on its monopoly leveraging theory that M3 had been required to prove that the change in Bard's gun had been made "for predatory reasons, *i.e.*, for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of the gun." (87a). While Bard disputed this and other evidence the majority held that:

> The evidence was sufficient to support the jury's verdict on that point and also support the jury's conclusion that Bard maintained its monopoly position by exclusionary conduct, to wit, modifying its patented gun in order to exclude competing replacement needles.

(87a).

Judge Newman wrote a dissenting opinion. It is based on arguments never advanced or preserved by Bard in the trial court or on appeal. Because these arguments had never been briefed, Judge Newman was left to make assumptions about the facts and record below – many of which are simply incorrect.

For example, Judge Newman assumed that Bard's gun modification was a product "improvement" and states that it would be "novel and pernicious" to allow a product improvement to constitute an antitrust violation. (58a-59a). The jury, however, was instructed that "offering better products or services" or the "introduction of superior products" can "never be found to be exclusionary" (A 10113, A 10120-1) and, as the majority opinion points out, Judge Newman's "premise . . . is contrary to the jury's verdict, which was supported by the evidence."

(87a-88a). Indeed, the evidence showed that Bard's gun modification reduced its performance. (A 8871-3).

Similarly, Judge Newman opines that the jury instructions should have explained in more detail the lawful right of a patentee to exclude others from making the patented invention. (57a, 62a). Exactly what Judge Newman believes the instructions should have said is unknown and, as the majority opinion points out, Bard did not object to the instructions at trial or on appeal. (88a). As a result the majority held "the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal." (88a).

Judge Newman further states that by using a simple adapter clip, M3's customers could have continued to use M3's flangeless needles in Bard's modified gun. (58a). Indeed, Judge Newman states that the need to use the adapter "is the antitrust ill of which M3 complained." (*Id.*). This argument was never advanced by Bard.

In fact, after Bard modified its monopoly gun, M3 did make one prototype of a an adapter clip that would allow its non-infringing flangeless needle to work in Bard's modified gun. (A 9162, A 9136-7). The clip, however, was unsafe. It could be easily dislodged and therefore presented a danger of patient injury. As a result, only the one prototype clip was ever made and none were ever sold or distributed. (A 9056-7, A 9136-7, A 9340-1).

Finally, Judge Newman states that Bard's monopoly power over the needle market is based on its '056 patent and is therefore lawful. (58a). This conclusion completely ignores that (1) the trial and appellate courts both held the '056 patent to be invalid and (2) M3's flangeless

needle did not infringe the '056 patent in any event. (A 14). M3, therefore, would not have been excluded from the market by the '056 patent even if it had been valid. Only modification of Bard's gun could accomplish that result.

4. Bard's Petition for Rehearing

After the Federal Circuit affirmed the monopoly leveraging claim, Bard filed a Petition for Rehearing and Suggestion for Rehearing In Banc. Bard's petition quoted extensively from Judge Newman's dissenting opinion and argued "Judge Newman's analysis is correct." (Pet. Reh. 11-12). This was the first time – either at trial or on appeal – that Bard had asserted *any* of the arguments raised in Judge Newman's dissent.

The petition for rehearing and suggestion for rehearing in banc were both denied. (90a-91a). Circuit Judge Gajarsa, joined by Judge Clevenger, wrote an opinion concurring in that order. (92a). In their concurring opinion they pointed out that no "fundamental issues at the intersection of patent law and antitrust law were being decided" by the Federal Circuit. (92a). In addition, their concurrence states (93a):

> the *only* argument Bard made on appeal regarding the antitrust violation was directed to the sufficiency of the evidence on this issue. Bard did not argue that modification of a patented product . . . cannot, as a matter of law, constitute an antitrust violation. Nor did Bard challenge the jury instructions. . . . In light of our limited review of jury findings, the majority affirmed the jury verdict based on its determination that

there was substantial evidence to support the verdict.

Consequently, this case does not establish or endorse a new antitrust theory.

B. The "On-Sale" Bar Patent Question

Bard attempts to mislead the Court into believing that the Federal Circuit's use of the "totality of the circumstances" test in determining whether three offers for sale were invalidating, caused it to decide that question differently than it would have if it had employed the more recent test set forth in *Pfaff v. Wells Elecs., Inc.*, ___ U.S. ___, 119 S. Ct. 304 (1998). In so doing, Bard suggests that the Federal Circuit was not aware of this Court's decision in *Pfaff* at any time during its consideration of the on-sale bar issue in this case. That is simply untrue.

First, in anticipation of *Pfaff*, the Federal Circuit panel expressly affirmed facts that meet the *Pfaff* test. Second, *after* this Court rendered its decision in *Pfaff*, the entire Federal Circuit considered Bard's Petition for Rehearing and Suggestion for Rehearing In Banc, which requested the court to re-evaluate the three invalidating offers for sale in this case in light of the issues raised by *Pfaff*. (Pet. Reh. 8-9). In ruling that rehearing was neither appropriate nor necessary, the Federal Circuit implicitly confirmed that this Court's decision in *Pfaff* does not require a different result than the one reached earlier by the appellate panel.

1. Statement of Facts Pertaining to the Patent Question

Under the *Pfaff* test, the facts in this case present a much stronger basis for finding an invalidating offer for sale and an invalidating actual commercial sale than do the facts in *Pfaff* – where the offer was still held to be invalidating. While *Pfaff* involved only a single sale of an invention *prior to the development of any physical embodiment of the invention*, the present case involves the following:

- an offer to sell the invention based upon detailed drawings *and existing commercial prototypes* that were successfully tested (the Phelps transaction) (70a-72a, 75a);
- a second invalidating *offer to sell* bulk quantities of the *existing physical embodiment* of the invention at volume discount rates (81a, 84a-85a); and
- the *sale* (*and delivery*) of a commercial quantity of *operable* needles and guns (*i.e.*, 250 needles and 10 guns) (81a, 84a-85a).

Simply put, each of these offers for sale or actual commercial sale meets and surpasses the *Pfaff* test for invalidating Bard's patent.

a. The November 12, 1984 Offer for Sale to Dr. Phelps

The offer to sell the second generation system to Dr. Phelps was a clear attempt to commercialize not only the biopsy gun but also the '056 needle. On September 25, 1984, Dr. Phelps wrote to Bard's predecessor, Radiplast,

seeking information about an earlier generation device pictured in a brochure. (A 13909). On November 12, 1984, Mr. Engstrom responded on behalf of Radiplast by offering to sell Dr. Phelps the "generation No. 2" (*i.e.*, the '056) biopsy gun and needles. In his letter to Dr. Phelps, *more than twenty months prior to the filing date of the patent in question*,[3] Mr. Engstrom stated:

> If you do not want to wait until we have our representation in USA arranged, *you can allways [sic] order the device directly from us. Our price for the device is SEK 9.900, – and for the needles SEK 75, – /ea.*
>
> The device is reusable and can be autoclaved. Very little service has to be done on the device due to reliable design. The needles are disposable and are designed to suit the device. (A 13911).

Actual physical embodiments of these needles had been tested and approved by Radiplast one month before Engstrom sent his offer of sale. On September 28, 1984, the manufacturer transmitted twelve physical samples of the needles expressly for the purpose of testing. (A 13945). On October 14, 1984, Mr. Engstrom wrote to the manufacturer:

> Biopsy needles: Enclosed please find our order for tooling and engineering. We approve your design of the plastic parts. (A 13947).

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[3] The patent in question was applied for on July 30, 1986 and originally issued as the '154 patent. It reissued in 1992 as the '056 patent. (5a-6a).

Accordingly, at the time of the offer to sell needles to Dr. Phelps, a physical, operable construction of the needle had been made, tested, and approved; and production tooling had been ordered.

b. Radiplast's Invalidating Sale of 10 Operable Guns and 250 Needles to a Potential Distributor

In June 1985, Radiplast again attempted to commercialize its invention more than one year before the filing date of the '154 patent. At that time, Radiplast sold and delivered 10 biopsy guns and 250 needles to a potential U.S. distributor, Pharmaseal, as part of its "marketing strategy." (A 8166-7, A 13825-27). Radiplast issued invoices for the 10 biopsy guns and for the 250 needles to Pharmaseal and requested payment. (A 13829-31). Moreover, Pharmaseal acknowledged to doctors and hospitals that it would be "conducting this field trial as a potential sales/distribution system for the Radiplast" needles. (A 13974). Therefore, the Pharmaseal "market study" itself constituted an invalidating sale and the actual delivery of commercially useable needles long before the critical date.

c. Radiplast's Invalidating Bulk Sale of Needles

Radiplast again commercialized its invention more than one year prior to the filing date of the '154 patent on January 21, 1985. At that time Radiplast offered via telex to sell Pharmaseal 10,000, 20,000 and 50,000 needles at volume discount rates:

> In quantities from 500 – 4000 PCS of the reusable device the price will go down to approx. 500 – 200 US DLRS/ea. For the needles the price will be for 10000 4.6 US DLRS/ea. 20000 4.3 US DLRS/ea. and for 50000 4.20, all bulk packed. Orders should be sent to us for both reusable and disposable device. Delivery of the needles will be made from Hart Ent. Direct to you. (A 13679).

The prices quoted by Radiplast not only represented a firm offer, but also a 60% profit on the needles for Radiplast. (A 8292-4, A 13929-30, A 13679). This bulk sale promotion constituted the very type of invalidating offer to sell commercially available products that § 102(b) is intended to prevent and easily meets the standard set forth in *Pfaff*.

2. The Patent Ruling In The District Court

The jury was instructed without objection on the issue of the on-sale bar and rendered special verdicts in favor of M3 on each asserted patent claim. (A 9). In particular, the jury found that the '056 patent was invalid and not infringed "because the claimed invention was . . . on sale in the United States more than one year prior to the actual date of filing of the application. . . . " (*Id.*).

3. The Patent Ruling In The Federal Circuit

Notwithstanding Bard's mischaracterizations, a majority of the Federal Circuit panel held that the '056/'154 patent was invalid due to the two offers to sell

and one actual sale referenced above. As stated by Chief Judge Mayer, the Federal Circuit "*may affirm the invalidity verdict on either basis.*" (67a) (emphasis added). Moreover, Judge Bryson succinctly stated "I agree with Chief Judge Mayer that the '056 patent is invalid under the 'on-sale bar' of 35 U.S.C. § 102(b)." (79a).

At the time the Federal Circuit issued its ruling in this case, it was well aware that *Pfaff* was awaiting decision in the Supreme Court. The opinions of both Chief Judge Mayer and Judge Bryson clearly anticipate and track the elements of the *Pfaff* test. Chief Judge Mayer segmented his analysis into (1) whether Bard's actions constituted an offer ("I. Offer for Sale") and (2) the status of the invention at the time the offer was made ("II. Offer of the Claimed Invention"). This is identical to the analysis required by *Pfaff*.

In conducting that analysis, both Chief Judge Mayer and Judge Bryson held that the offered products were reasonably expected to work for their intended purpose. (75a-76a, 81a-85a). For example, Chief Judge Mayer held that "the evidence suggests at the very least that Radiplast had reason to expect in November 1984, that its needle would work for its intended purpose . . . " and "that Radiplast had more than a mere conception from which it was working towards development." (77a). In addition, Chief Judge Mayer held that Mr. Engstrom made a commercial offer for sale to Dr. Phelps, stating "Engstrom's letter [of November 12, 1984] is a clear offer for sale of the second generation device and the biopsy needles." (72a). Chief Judge Mayer also held that "the alterations made after the offer for sale to Phelps did not address inventive aspects of the '056 patent's new biopsy

needle" (75a) and concluded that "Bard's evidence shows nothing beyond unclaimed mechanical adjustments to the needle design." (77a).

Judge Bryson similarly found invalidating commercial offers for sale of a device that was ready for patenting: "It is undisputed that the June 1985 transaction constituted a sale and that the needles sold at that time embodied the invention of the '056 patent." (81a). Judge Bryson also considered the offer to sell up to 50,000 needles to Pharmaseal and stated "[t]he offer of such large quantities of needles was clearly for commercial, rather than experimental, purposes, and by June 1985 it was clear that the needles that were being offered to Pharmaseal embodied the later-claimed invention." (84a). Judge Bryson also found that experimentation was not required and that Radiplast knew the needles would work for their intended purpose. (81a-83a). Simply put, the needle was ready for patenting. Indeed, it had already been *reduced to practice*, at the time each commercial offer for sale was made.

4. Bard's Petition for Rehearing

This Court decided *Pfaff* on November 10, 1998. Bard's Petition for Rehearing and Suggestion for Rehearing In Banc was not denied until December 7, 1998 – almost a month later. With the benefit of the *Pfaff* decision, the original panel and the circuit as a whole declined to rehear Bard's arguments. (90a-91a). This action by the Federal Circuit implicitly confirms that the

panel's original holding with regard to the on-sale bar issue is not inconsistent with *Pfaff*.

REASONS FOR DENYING THE WRIT

A. The Antitrust Question

The petition does not allege a conflict between the opinion of the Federal Circuit and any other circuit or this Court on the antitrust issue. Apparently Bard's request for review is based on Supreme Court Rule 10(c), which allows for review if "a United States Court of Appeals has decided an important question of federal law that has not been, but should be, settled by this Court."

The antitrust question on which petitioner seeks review, however, was not preserved and was not before the appellate court. As a result, the Federal Circuit plainly stated that the question of whether the modification of a patented product can ever violate the antitrust laws was not being decided. Furthermore, M3's fact-bound monopoly leveraging claim is not a new antitrust cause of action; nor are any novel and critical issues pertaining to the intersection of the patent and antitrust laws presented by the petition.

1. Bard requests that this Court consider whether a patentee with monopoly power may modify his patented product so as to monopolize a second relevant product market without violating the Sherman Act. At trial, however, Bard requested no jury instructions on this subject and did not object to the conventional antitrust instructions given. In its main appeal brief, Bard did not raise

this subject and the majority opinion of the Federal Circuit explicitly stated that Bard had not raised and the court was not deciding such question. (88a). Rather, the Federal Circuit explicitly stated that it was only deciding that there was a sufficient evidentiary basis for the jury to return a verdict for M3 on its monopoly leveraging claim pursuant to the unchallenged instructions given. (*Id.*).

Similarly, in denying rehearing in banc, Judges Gajarsa and Clevenger made clear that the Federal Circuit (1) did not have before it and had not decided the antitrust question on which petitioner seeks review; (2) had decided only the fact-bound question of whether the evidence in this case was sufficient to sustain the verdict under the instructions given; and (3) that as a result "this case does not establish or endorse a new antitrust theory." (92a-94a).

This Court has consistently refused to decide questions of law not decided by an appellate court or not preserved by objection to the instructions at trial. *City of Springfield v. Kibbe*, 480 U.S. 257, 258-59 (1987) (writ of *certiorari* dismissed because "we ordinarily will not decide questions not raised or litigated in the lower courts," especially where party seeking to argue the issue failed to object to the jury instructions); *E.E.O.C. v. Federal Labor Relations Authority*, 476 U.S. 1924 (1986) (writ of *certiorari* dismissed because "our normal practice . . . is to refrain from addressing issues not raised in the court of appeals."); *Addickes v. S.H. Kress & Co.*, 398 U.S. 144, 147 n. 2 (1970) (Supreme Court will not review a question not pressed or passed on in the court below).

2. The question of whether the owner of a valid patent who enjoys monopoly power in the market for the patented product can modify his patented product so as to monopolize a second market is not raised by the decision below for yet another reason. Here, the '056 patent which covered Bard's automatic gun and needle (A 13589) was held invalid due to an on-sale bar by both the trial and appellate courts. (2a-3a). Therefore, Bard had no right, incident to a *valid* patent, to exclude competitors from making biopsy needles. Despite this fact, Bard blithely assumes throughout its petition that the '056 patent is valid and that the application of the antitrust laws therefore has to be altered to accommodate the lawful right of a patentee to exclude infringers.[4]

Furthermore, the trial court held that M3's flangeless needle did not infringe the '056 patent. (A 14-17).[5] Thus, even if the '056 had been found valid, it provided no lawful basis to exclude from the relevant market M3's non-infringing, flangeless needles.

3. Bard states that it modified its gun "within the scope of the ['056] patent." Nothing could be further from the truth. Bard modified its gun by removing the rear

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[4] *See, e.g.*, Petition at 15, where Bard argues that the Federal Circuit created a new antitrust cause of action by "disregarding Bard's rights as a patentee [of the '056 patent]"; *see also* Petition at 16-17, where Bard argues that the '056 patent gave it the lawful right "to exclude competitors from making, using or selling the needles used with Bard's patented modified device."

[5] Because the Federal Circuit found the '056 patent invalid it had no need to reach the question of whether the trial court erred in holding that M3's flangeless needles did not infringe that patent. (3a).

push plate or sled. (A 8327-32, A 8768-73, A 8871-2, A 14517). The '056 patent had 23 claims. (A 13589). The rear push plate, however, is not a claimed feature in any one of them. In fact, there is not one single word pertaining to the rear push plate in the '056 patent.

It is therefore clear that, even if the '056 patent were valid (which it was not), Bard modified an unpatented feature of its gun for the sole purpose and with the effect of monopolizing a second relevant market. Whatever antitrust issues this conduct raises, it has nothing to do with the intersection of the patent and antitrust laws because the anticompetitive product modification was with regard to a feature on which no patent rights were ever claimed.

4. This Court has long held that use of monopoly power in one market to obtain monopoly in a second market is a violation of § 2 of the Sherman Act. For example, in *United States v. Griffith*, 334 U.S. 100, 107-08 (1948), this Court held that the use of monopoly power in certain geographic markets to "beget monopoly" in other markets to be illegal, stating: "the use of monopoly power, however lawfully acquired, to foreclose competition, to gain a competitive advantage, or to destroy a competitor, is unlawful." *Accord*, *Otter Tail Power Co. v. United States*, 410 U.S. 369 (1973) (use of monopoly power over power transmission lines to obtain monopoly over retail distributor held unlawful); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir.), *cert. denied*, 439 U.S. 838 (1978) (use of monopoly power over patented products to exclude competitor from other product markets held unlawful); *Alaska Airlines v. United Airlines*, 948 F.2d 536, 548 (9th Cir. 1996) (use of monopoly power "in

the first market to acquire or maintain a monopoly in the second market" violates § 2).

In this case, Bard had monopoly power over the gun market. Without that power, Bard would have lost gun sales if it reduced the quality of its gun or modified the gun so as to exclude the use of competing needles which customers wanted to use. Because it enjoyed monopoly power over the gun, consumers were without adequate gun alternatives and had to continue to purchase the Bard gun and therefore to use only the Bard needle. This is a classic use of monopoly power over one market to exclude competitors from and obtain a monopoly in a second market. There is nothing novel about this theory. It is conventional and well-established antitrust doctrine which does not necessitate review by this Court.

5. Bard also claims that it is novel and unprecedented to hold that one who modifies a product for the purpose and with the effect of monopolizing a related market has violated the Sherman Act. Even if Bard had preserved this argument (which it has not), it is without merit.

For example, in *In re IBM Peripheral EDP Devices Antitrust Litigation*, 481 F.Supp. 965, 1003 (N.D. Cal. 1979), *aff'd sub nom., Transamerica Computer Co. v. International Business Machine Corp.*, 698 F.2d 1377 (9th Cir. 1983), the court addressed product changes by a monopolist and stated:

> if the only purpose and effect of the change was to gain a competitive advantage in the terminal market (where the monopolist lacked monopoly

> power), that use of monopoly power would be condemned.
>
> * * *
>
> If the design choice is unreasonably restrictive of competition, the monopolist's conduct violates the Sherman Act.

Accord, Northeastern Telephone Co. v. American Telephone and Telegraph Co., 651 F.2d 76, 94-96 (2d Cir. 1981) (intentionally designing couplers to impede competition in the terminal market held to be a predatory act that would support Sherman Act violation). *See also* 1 ABA Antitrust Law Developments, 286 (4th ed. 1997) (where evidence indicates that product modification does not improve performance or lower cost and sprang from anticompetitive motives, violation may result).

In this case, the evidence showed and the jury found that Bard's modification of the biopsy gun did not improve performance or make the product better. It made the product worse. Bard's sole intent was to exclude the competing, non-infringing, flangeless needles from the market. (A 14504-05, Pet. 6). There is nothing novel or pernicious about holding such blatantly anticompetitive conduct illegal.

B. The Patent Question

1. Bard Has Failed to Allege A Proper Basis for Review of the Patent Holding

Bard's Petition fails to advance any cognizable basis for reviewing the patent decision below. In particular, Bard cannot allege that the Federal Circuit has "so far

departed from the accepted and usual course of judicial proceedings" or that it has "decided an important question of federal law that has not been, but should be settled by this Court or has decided an important federal question in a way that conflicts with relevant decisions of this Court." Supreme Ct. Rule 10(c). Rather, Bard merely intimates that the Federal Circuit's decision is incorrect even after it was reviewed by the entire court *subsequent* to this Court's decision in *Pfaff*. As detailed above, however, the facts and circumstances of this case far exceed the test set forth in *Pfaff*.

2. The Decision Below Is Consistent with *Pfaff*

Pfaff holds that in order to invalidate a patent under 35 U.S.C. § 102(b) that prior to the critical date there must be 1) a commercial offer for sale; and 2) the device must be ready for patenting – meaning that it has either been reduced to practice or drawings or descriptions exist which are capable of enabling one skilled in the art to practice the invention. *Pfaff*, ___ U.S. at ___, 119 S. Ct. at 312.

While the patentee in *Pfaff* did not have a prototype or reduction of the invention to practice until *after* the critical date, this Court still held that the device was offered for sale *prior to* the critical date due to the existence of drawings that were sufficiently clear and precise so as to enable one skilled in the art to understand the device and put it into operation. Even in the absence of a prototype, *Pfaff* held that the device set forth in the drawings could be expected to work for its intended purpose

and that there was sufficient disclosure to allow for the filing of a patent application. *Id.* at 309-10. (A 1645).

The present facts go well beyond what is required by *Pfaff*. First, the Federal Circuit clearly and explicitly held that Radiplast's multiple offers for sale were commercial offers for sale as required by *Pfaff*. Second, unlike *Pfaff*, Radiplast not only had detailed drawings but had actually *reduced the invention to practice* in the form of tested and approved prototypes that were known to work for their intended purpose well before the critical date.

Accordingly, the decision of the Federal Circuit – which that court declined to reconsider after *Pfaff* was decided – is not at all inconsistent with any decision of this Court.

CONCLUSION

For the reasons given above, respondent respectfully submits that the Petition should be denied as to both the antitrust and patent questions on which review is sought.

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Respectfully submitted,

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No. 98-1373

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

C.R. BARD, INC.,

Petitioner,

—v.—

M3 SYSTEMS, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY MEMORANDUM

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PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of the petition for writ of *certiorari*.

Petitioner is C.R. Bard, Inc. ("Bard"). Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company or subsidiaries.

No. 98-1373

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

C.R. BARD, INC., *Petitioner,*

v.

M3 SYSTEMS, INC., *Respondent.*

PETITIONER'S REPLY MEMORANDUM

I. THE ANTITRUST ISSUE WAS RAISED ON APPEAL

Contrary to M3's assertions, *see, e.g.*, Brief in Opp., pp. 4, 5, 7, 16-17, Bard has consistently argued, *inter alia*, in its JMOL motions to the district court and in its briefs to the Federal Circuit that, as a matter of law, Bard's modification of its patented biopsy device is not a violation of the antitrust laws *and* that the evidence presented by M3 is not sufficient to support a properly formulated antitrust claim. *See, e.g.*, A5354-56 (Bard's JMOL motion); Bard's Brief and Reply Brief for Plaintiff-Appellant, pp. 49-50 and p. 25, respectively). For example, at pages 49-50 of Bard's Brief for Plaintiff-Appellant, the antitrust issue is clearly presented:

> This leaves M3 Systems' third theory that when Bard modified it Biopty gun so that M3 Systems' current ACN needle would no longer work, it was guilty of monopolization or attempted

> monopolization. However, the gun modification, based upon the undisputed evidence, does not violate the antitrust laws. M3 Systems' own expert DeBrock admitted that absent an injunction that would issue if Bard prevails in this litigation, M3 Systems could effectively compete [A9104-05; A13169-73].

In considering the antitrust issue, the Federal Circuit only suggested that Bard had waived its ability to contest the sufficiency of the jury instructions. 88a. Bard's petition for writ of *certiorari*, however, is not premised upon the propriety of the jury instructions, but rather on whether, as a matter of law, Bard's modification of its patented device can constitute an antitrust violation, and whether sufficient evidence was presented at trial to support a properly formulated antitrust claim.

M3's argument that Bard waived the antitrust issue because of its failure to object to the jury instructions is incorrect. *See, e.g.*, Brief in Opp., pp. 7, 16-17. Bard was not required to expressly challenge individual jury instructions to preserve the antitrust issue for appeal. *See City of St. Louis v. Praprotnik*, 485 U.S. 112, 120 (1988):

> Although the same legal issue was raised both by [the JNOV] motions and by the jury instruction, "the failure to object to an instruction does not render the instruction the 'law of the case' for purposes of appellate review of the denial of a directed verdict or judgment notwithstanding the verdict." (citation omitted).

Moreover, the Court has recognized that a party is not required to contest the jury instructions when arguments

regarding the sufficiency of evidence are raised. *Boyle v. United Technologies Corp.*, 487 U.S. 500, 513-514 (1988) (the failure to object to jury instructions does not waive an issue "[i]f the evidence presented in the first trial would not suffice, as a matter of law, to support a jury verdict under the properly formulated defense. . . .").

M3's contention that Bard did not preserve the antitrust issue on appeal because Bard's arguments to the Federal Circuit were not as detailed as M3 would have preferred is similarly misplaced. Brief in Opp., p. 5. *See, e.g., City of St. Louis*, 485 U.S. at 120 (arguments which "were much less detailed than the arguments it now makes in response to the decision of the Court of Appeals" does not imply "that petitioner failed to preserve the issue raised in its petition for certiorari").

Whether Bard's modification of its patented device within the scope of the patent, which rendered M3's replacement needles incompatible with the modified device, can constitute a violation of the antitrust laws was clearly raised by Bard before the district court and Federal Circuit[1], and was specifically addressed in both the majority (86a-88a) and the dissenting opinions (56a-62a). The antitrust issue was clearly preserved on appeal, and is

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[1] On appeal M3 maintained that Bard was precluded from arguing that modification of its patented device was not an antitrust violation based on M3's contention that the issue was not raised in Bard's pre-verdict JMOL motion. *See* M3's Brief for Defendant-Appellee, p. 48. Bard responded that the issue was raised in its pre-trial JMOL motion, and that M3 had failed to preserve its waiver argument in M3's post-verdict JMOL motion. *See* Bard's Reply Brief for Plaintiff-Appellant, pp. 1-3 (citing *Collins v. Illinois*, 830 F.2d 692, 698 (7th Cir. 1987) (waiver argument is waived if not argued in response to JNOV motion)). The Federal Circuit's failure to comment upon M3's waiver argument illustrates that M3's position is incorrect.

now properly before this Court. *See, e.g., Stevens v. Department of the Treasury*, 500 U.S. 1, 8 (1991) (issue preserved since the "Court of Appeals, like the District Court before it, decided the substantive issue presented").

II. THE "ON SALE" DECISION IS IN CONFLICT WITH THE COURT'S DECISION IN *PFAFF*

M3 does not contest that the conflicting Federal Circuit opinions are expressly premised on the often criticized, "unnecessarily vague" and now rejected "totality of the circumstances" test. *See* 69a, 70a, 82a-83a. Rather, M3 argues that (a) the Federal Circuit's September 1998 decision is "consistent with" and "clearly anticipate[s] and track[s]" the Court's later decision in *Pfaff, see* Brief in Opp., p. 14, 22-23; and (b) the Federal Circuit's *en banc* decision "implicitly confirmed" *sub silentio* the Court's intervening *Pfaff* decision, *see* Brief in Opp., pp. 9, 15-16. M3's arguments are incorrect and do not address the undisputed fact that the Federal Circuit relied upon the now rejected "totality of the circumstances" test. Further, M3 fails to explain how an analysis under the old "totality of the circumstances" test can be used to support a holding under the Court's new *Pfaff* precedent. *Pfaff v. Wells Elec., Inc.*, ___ U.S. ___, 119 S. Ct. 304 (1998).

Without citation, M3 attempts to mislead the Court by suggesting that the Federal Circuit found Bard's invention was reduced to practice prior to the critical date. *See, e.g.*, Brief in Opp., pp. 15, 23. The Federal Circuit made no such finding. Moreover, M3 can point to no finding in any of the three opinions which comprise the Federal Circuit decision that Bard's invention was "ready for patenting" prior to the critical date. For example, it is not disputed that prior to the critical date, there were no

drawings of the patented device, and only preliminary drawings of a needle concept, the design of which was later changed. 27a, 72a-73a. No evidence bridges the gap between the "detailed engineering drawings" of *Pfaff* and the absence of any drawings of the device, or the preliminary drawings of a needle concept which was "in an early development stage". 30a. *See id.* at 307. Clearly, Bard had not "prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention" prior to the critical date. *See id.* at 312. The Federal Circuit's split decision premised on the rejected "totality of the circumstances" test should be vacated and remanded for further consideration in light of the *Pfaff* decision.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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